

1 it does to you. I am talking about health effects.

2 MS. PATTON: This is the point I made earlier,
3 many of these people did initially make claims of health
4 effects. We did not have them present testimony on those
5 claims because of the reason you are talking about, the
6 documentation of those claims is very difficult in some
7 cases.

8 DR. BRICK: Was there any pattern in these
9 claims, health similarities or adverse effects?

10 MS. PATTON: This is not a part of our hearing
11 record. I will comment to you that in some cases it
12 did come out but it was not part of the planned
13 testimony.

14 I can give you information from our witnesses
15 but it was not part of the hearing record.

16 Most of these people experienced a generalized
17 kind of malaise in the sense of vomiting and nausea,
18 headaches. They report flu like symptoms. This is not
19 all of the people but some of them.

20 It is a pattern that goes with varying parts
21 of that spectrum. I cannot tell you anything more
22 definite than that. In some cases they did have medical
23 documentation but we did not go into that for our hearing.

24 DR. BRICK: Thank you.

25 CHAIRMAN SHEPARD: Major Brown?

1 MAJOR BROWN: Did EPA in its label usage
2 designation require the applicator to apply the pesticide
3 aerially for under certain conditions, mainly, wind
4 conditions?

5 MS. PATTON: In some cases it is the labels
6 and in some cases it is state legislation. This is one
7 of the things that is very variable across the country.

8 Many states do have requirements that it be
9 required only when the wind is less than seven miles
10 per hour or five miles per hour, the humidity is below
11 a certain point and the temperature is below a certain
12 point. This is to avoid volatilization drift.

13 The label has certain restrictions along that
14 line although not as to temperature. The label says
15 "keep out of water," without telling you how you are
16 supposed to keep it out of water.

17 Oregon is one example of a state that has
18 fairly stringent regulations in the sense that they
19 require buffer strips in certain cases.

20 Across the country it is quite variable in
21 terms of what the real requirements are.

22 The EPA labels say "keep out of water" plus
23 a few other things. It does not have itemized
24 prohibitions on use in a broad sense. It does in a
25 narrow sense.

1B

1 CHAIRMAN SHEPARD: Dr. Lingeman?

2 DR. LINGEMAN: Did you say that EPA is not,
3 addressing the health effects?

4 MS. PATTON: We have not presented testimony on
5 it.

6 DR. LINGEMAN: Is anyone in the country, in any
7 agency systematically keeping track of people who complain of
8 symptoms relating to those incidents?

9 MS. PATTON: The EPA keeps a file on the
10 claims. There are numerous claims. The problem is with
11 documentation of the claims. For the attorneys and
12 scientists working on the case, this has been one of the
13 most difficult tasks, locating records to document the
14 things people say. In some cases we find them and in
15 some cases we do not.

16 EPA plus a number of state agencies do in
17 fact keep records of the reports people make to them. In
18 some cases they are investigated and in many more cases,
19 they are not investigated either by EPA or other sources.

20 I think the reason they do not investigate,
21 when you talk to the people, is partly resources, partly
22 it is not knowing what they will do once they investigate.
23 I think it is that kind of a situation.

24 I do not want to overstate the case. There
25 are reports that do exist. I would say for the most part

1 they are uninvestigated.

2 DR. LINGEMAN: Maybe there should be a
3 national register of complaints filed in a systematic
4 manner similar to the one with the VA's register for
5 veterans.

6 MS. PATTON: EPA does collect those. It is
7 a matter of the follow-up. That is where the question
8 lies.

9 CHAIRMAN SHEPARD: What part of EPA is doing
10 that?

11 MS. PATTON: Mr. James Boland and Mr. Frank
12 DeVito are the persons that I think of being in charge.
13 This is called the PIM system, pesticide incident
14 monitoring system. Other state agencies feed into it.

15 Some of our case histories are located there.
16 Others we located in the state offices themselves. In
17 not all cases does it reach EPA.

18 There are a number of institutions that have
19 things in place to deal with it but I am not sure just
20 how coordinated it is.

21 CHAIRMAN SHEPARD: Dr. Murphy?

22 DR. MURPHY: You mentioned you did have
23 a presentation regarding epidemiology. You mentioned
24 the Alsea, Swedish and German studies.

25 Can you comment regarding the status of the

1 validity of those studies?

2 MS. PATTON: I would rather not. I am just
3 trying to be judicious. Testimony is yet to come both
4 from EPA and Dow on all of those studies. I think it is
5 inappropriate for me to comment at this time.

6 DR. MURPHY: We have at various times heard
7 from EPA sources, I think, public and private, that the
8 Alsea study was good, that it was not so good, that it
9 had changes of position.

10 In a nutshell, how did the presentations come
11 off, equivocal or unequivocal?

12 MS. PATTON: Just on the Alsea study?

13 DR. MURPHY: Yes.

14 MS. PATTON: (Pause.)

15 DR. MURPHY: That is all right.

16 MS. PATTON: My silence should not be
17 interpreted to mean anything other than I am an attorney
18 attempting not to make any comment on the case.

19 DR. MURPHY: Thank you. I might say we are
20 very privileged to have Ms. Patton here. We should make
21 an attempt not to put her on the spot. She is in a very
22 sensitive position.

23 Dr. Suskind?

24 DR. SUSKIND: I have one comment and one
25 question. With respect to the Alsea study, those of you

1 who are not aware of it, there are two reports from
2 Oregon State University which attempts to assess the
3 validity of that study. I would refer you to that study.
4 There are two volumes to wit. It was supported by
5 the NIEHS.

6 I will not comment on the conclusions of that
7 study. I will leave it to the reader to draw conclusions
8 for him or herself.

9 The question is about the incidents reported
10 which involved farm animals and which involved wildlife.

11 Is there any information you can give us
12 about that even though the clinical information is
13 perhaps not really discussable?

14 MS. PATTON: I am trying to limit myself to
15 the testimony that has been presented as opposed to the
16 other information that we keep receiving.

17 Because of the documentation problem, we did
18 not present directly any testimony on the farm animal
19 effects, even though the PIM system has such reports.

20 Attempting to trace them back and get
21 veterinarian confirmation reports, we find it does not
22 exist, not that they investigated and found nothing but
23 for the most part, it was not investigated.

24 People planned to take the animals they thought
25 had been affected and they did not follow up or they took

1 them to someone who did not examine them. It is a
2 situation again of very limited follow-up.

3 The reason the case histories were limited to
4 the residue and pathology information was that was the
5 one place where there was follow-up.

6 We did have testimony from a witness in Oregon
7 and this is in the hearing record, although it came out
8 on cross examination. It was not a part of her direct
9 testimony. In one of the Oregon forest areas, there had
10 been reports of high incidences of abortion in sheep, I
11 believe, near a spray area in Oregon.

12 That was undocumented. It was a sheep
13 population that prior to spraying had given birth to
14 so many offspring on a regular basis for a number of
15 years and then in a certain year following spraying,
16 there were 13 abortions which was very unusual to these
17 farmers.

18 We know nothing more about it than that. It
19 came out on cross examination. It was not something we
20 had asked the witness to testify about on her direct
21 testimony.

22 I cannot tell you anything more than that.
23 There are many reports. The PIM system has them. Our
24 rebuttal files have them, but they have not been
25 investigated.

1 DR. SUSKIND: Are there any reports on effects
2 on wildlife, on birds, forest mammals? When DDT was
3 studied thoroughly or not so thoroughly, one of the
4 obvious effects was on avian species and on other
5 wildlife.

6 MS. PATTON: I am not aware of any studies
7 in that area besides the studies of Dr. Young at
8 the Egland Air Force Base. His studies, according to
9 his testimony, indicate there are no such effects. This
10 is his testimony. How this will be presented down the
11 line, I cannot comment on at this time.

12 Let me back up on one point on your question
13 about the Alsea study. Is it correct that NIEHS did
14 support the Oregon State study?

15 DR. ROGAN: There is money for an
16 administrative study and ad hoc studies, things like
17 that being appropriated that do not require a separate
18 grant. Whether or not those studies were funded out of
19 that area, I do not know.

20 I do not know of a specific grant put in
21 to do those analyses of Alsea I and Alsea II. I think
22 the time span was too short. If it was funded by NIEHS,
23 it was done so on that basis.

24 MS. PATTON: I was just trying to clarify that
25 in terms of your record. That was the first time I had

1 heard NIEHS had sponsored it.

2 Anyone is welcome to the testimony of our
3 witnesses. The transcripts are available. If anyone
4 wants to review the cross examination of our witnesses,
5 they are perfectly free to do so. I would be glad to
6 send you transcripts.

7 I just did not want to comment on my own views
8 of how that went. I will be pleased to send transcripts
9 so you can make your own judgments. We can send you
10 both the written testimony and the cross examination if
11 you wish.

12 CHAIRMAN SHEPARD: Thank you. Dr. Brick?

13 DR. BRICK: As a general question and this
14 has nothing to do with your case, since you are an
15 attorney, there must have been some legal cases that
16 have been brought against the sprayer, et cetera, by
17 civilians who allege certain health effects.

18 Where can you get such information? Are you
19 aware of any such cases? How would you become aware of
20 any such cases?

21 MS. PATTON: There are cases pending now.
22 Some people we considered to have as witnesses we decided
23 against having as witnesses precisely because they
24 had cases pending on this very question and we felt it
25 might be an interference one way or the other.

1 I am not aware of any cases that have been
2 decided at this point. I am not sure that many of them
3 are actually underway. There are a number of them in the
4 court that are very active right now.

5 DR. BRICK: Mr. Chairman, you might ask that
6 question of the General Counsel. I think it is worthwhile
7 to follow this up with reference to what Dr. Lingeman
8 pointed out, some sort of a register on civilians who
9 allege effects from dioxin, health effects.

10 CHAIRMAN SHEPARD: That is a good point,
11 Dr. Brick. I have made a note of that.

12 I think maybe when Dr. Honchar speaks about
13 the dioxin registry which I am very much looking forward
14 to, we can address some of that to her. It may well be
15 in the process of the dioxin registry, there is such an
16 effort ongoing.

17 Dr. Gross, did you have anything more you
18 wanted to add?

19 DR. GROSS: No, Mr. Chairman.

20 CHAIRMAN SHEPARD: Are there any other
21 questions for Ms. Patton?

22 (No response.)

23 CHAIRMAN SHEPARD: We really appreciate your
24 participation. Thank you for being here and bringing us
25 up to date. I think it is an area we are all very

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1 interested in and we will be following closely.

2 MS. PATTON: Thank you.

3 CHAIRMAN SHEPARD: I would like to remind our
4 guests that there will be an opportunity to ask questions
5 at the close of the formal agenda. I would encourage you
6 to write your questions down. Mrs. Williams will assist
7 you in that process. She has cards and writing materials
8 in the back of the room.

9 I understand some of you have not yet
10 registered. It is very helpful to us for all of you to
11 register. If you have not done so, please do so at any
12 point convenient to you.

13 I would like to deviate from the agenda
14 slightly. I want very much for Mr. Cleland to be here
15 for certain portions of the agenda but he is not due
16 to arrive for another few minutes.

17 I would like to turn the floor over to
18 Dr. Suskind and ask him to discuss two areas or to lead
19 the discussion in two areas.

20 As you all know, Dr. Raymond Suskind has been
21 following a number of the industrial exposures. We would
22 like to have him bring us up to date as to his efforts in
23 that area. If time permits, we would like him to lead
24 a discussion on the foreign articles that have been
25 alluded to so often.

1 Dr. Suskind?

2 REPORT ON FOLLOW-UP ON INDUSTRIAL EXPOSURE
3 DATA AND DISCUSSION ON SWEDISH AND WEST
4 GERMAN STUDIES - BY DR. RAYMOND SUSKIND

5 DR. SUSKIND: Thank you very much.

6 I have been asked to start the discussion of
7 the current status of industrially exposed workers in
8 the United States and also to introduce the discussion
9 on the studies in Sweden which I think most of the Panel
10 has reviewed or most of the Committee has reviewed, and
11 the West German report.

12 Insofar as the work going on in the United
13 States, I am aware of four studies relating to the two
14 populations. One, the population exposed in the Monsanto
15 plant in Nitro, West Virginia. The initiation of that
16 exposure was in 1948. The first evidence of any health
17 effects emerged from a run away reaction which occurred
18 in March of 1949.

19 The population in that plant was exposed to
20 a process making 2,4,5-T from 1948 until 1969.

21 A mortality analysis of workers who were
22 exposed to the run away reaction, the TCP run away reaction,
23 TCP is an intermediate in the manufacture of 2,4,5-T,
24 was completed and published. I think the Panel has
25 already discussed that at the last meeting.

A mortality analysis of workers in the same

1 plant, not only those exposed to the run away reaction
2 which totaled 122 and probably the most heavily exposed
3 to TCP and its contaminants from the kettle which was
4 involved, very similar to the Seveso episode.

5 The workers who were exposed from 1955 on
6 to the manufacture of 2,4,5-T, that probably will include
7 about 400 total employees. A mortality analysis is
8 being completed on that group.

9 In addition, 435 workers divided up into
10 three different cohorts were examined late last year by
11 a clinical epidemiologic study, hands on examination
12 and the three cohorts consisted of persons with a record
13 of adverse reactions, of chloracne and other symptoms,
14 other clinical findings, who were exposed to the process,
15 and an equal number or almost equal number of persons
16 without record of adverse effects who were exposed to
17 the process and then a control group of workers in the
18 same plant who were not exposed to the 2,4,5-T process.

19 The analysis of that data is in process and
20 we should have a preliminary report within the next
21 couple of months.

22 In addition to that population, there is a
23 study of workers in a plant which made pentachlorophenol
24 from the 1940's up until 1978 in Sauget, Illinois. In
25 that same plant, workers who were exposed to

1 pentachlorophenol were also exposed to ortho and
2 parachlorophenol. An examination was done last October.
3 The data from that study is just about completed and
4 an analysis should be out very shortly.

5 I do know the Dow group is continuing to
6 analyze the clinical information that it has accumulated
7 over the years of two populations that were exposed to
8 the manufacture of 2,4,5-T.

9 The first report about that first group was
10 published in the January issue of the Journal of
11 Occupational Medicine.

12 They are still gathering data on the second
13 group. I have no idea when that information will be
14 published.

15 Dr. Selikoff did an examination of the Nitro
16 group but examined active workers rather than a group
17 of cohorts which involved retirees as well as active
18 workers.

19 There may be others going on that I am not
20 aware of.

21 Perhaps we should pause and see if there
22 is discussion of groups in the continental United States.

23 CHAIRMAN SHEPARD: Are there any questions
24 for Dr. Suskind or any points of discussion?

25 Dr. Kearney?

1 DR. KEARNEY: Dr. Suskind, do you know the
2 status of the study at Jackson, Arkansas that is underway?

3 DR. SUSKIND: Jacksonville. The data is
4 being analyzed. This is the Vertec plant which made
5 2,4,5-T. Dr. Selikoff did a study, a hands-on
6 examination, and did get some environmental information
7 as well. I do not think that has been published yet.

8 DR. KEARNEY: We have heard much about these
9 studies. Do you have any idea of a timeframe in which we
10 will hear case by case the results of these
11 investigations?

12 DR. SUSKIND: As you well know, computerized
13 information which is programmed, sometimes it is not
14 easy to predict when the analysis is going to be
15 available. We thought for the Nitro study, that we would
16 have had this information before now. Unfortunately,
17 we have to compete for computer time and computer space
18 and epidemiologic and statistical resources with the
19 rest of our institutions.

20 I would assume with respect to the clinical
21 epidemiologic results in the Nitro group, we should have
22 a preliminary report in the next few months.

23 DR. HONCHAR: Dr. Suskind, I have a few
24 questions of a design nature with regard to some of the
25 studies you mentioned.

1 With respect to the mortality analysis of the
2 Nitro population, you mentioned 2,4,5-T was being
3 synthesized there starting in 1948 but you were looking
4 at the mortality experience of people exposed since 1955.

5 DR. SUSKIND: The employment statistics
6 apparently are not as accurate as they might be for the
7 period from 1948 to 1955.

8 It would be more important to have the
9 population -- we originally started out with that idea
10 that we were going to take the whole population from
11 1948 on.

12 The number of records apparently that were
13 missing, employment records, were such that the
14 epidemiology group felt it would be better to take the
15 group from 1955 on. That does not include the group
16 exposed to the run away reaction.

17 DR. HONCHAR: If I could ask you about the
18 control for that study. Can you easily summarize what
19 their exposures might have been? You said they were
20 from the same plant.

21 DR. SUSKIND: The plant manufactured 2,4,5-T
22 incidental to its major manufacturing objectives, and that
23 was to manufacture rubber additives. The plant
24 originally back in the 1920's was solely devoted to the
25 manufacture of rubber additives.

1 There are any number of compounds to which
2 people might have been exposed to which also were toxic.

3 The group that was exposed from 1950 on
4 some of them were exposed to paraminobiphenyl. There was
5 a small epidemic of bladder cancer.

6 Some of the workers in that 1955 to 1968 group
7 were also exposed to paraminobiphenyl and they developed
8 bladder cancers and they are still being monitored for
9 bladder cancer.

10 The population, the control population, is not
11 necessarily one which is exposed to non-toxic materials.
12 They also have been exposed to toxic materials.

13 I think this is a very important consideration.
14 I think in the Swedish studies we have a difficult time
15 knowing what else these people were really exposed to
16 in the case control studies.

17 CHAIRMAN SHEPARD: Good morning, Mr. Cleland.
18 We are most pleased that you could take time from your
19 busy schedule to be with us this morning.

20 MR. CLELAND: Thank you very much. Good
21 morning, all.

22 COMMENTS FROM THE ADMINISTRATOR OF VETERANS AFFAIRS

23 MR. CLELAND: You might have heard, but I
24 would like to bring to your attention a study just
25 released by the National Toxicology Program in regard to

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1 200 male mice who were examined and their offspring
2 failed to indicate that heavy exposure to simulated
3 Agent Orange resulted in a loss of fertility or an
4 abnormal number of offspring with birth defects.

5 Apparently the test examines some 3,000
6 near term fetuses and 2,000 live offspring.

7 According to Dr. James Lamb of the National
8 Toxicology Program, and I quote, "We failed to get any
9 indication of a significant increase in birth defects
10 or decreased fertility."

11 Also quoting from Dr. Lamb, "These data
12 therefore do not support the presumption that Agent
13 Orange is responsible for former Vietnam veterans
14 fathering children with an unusual number of birth
15 defects nor for the veterans experiencing a loss of
16 fertility."

17 What I would like for the Committee to do, if
18 you will, is look at this report and get back to me in
19 a month through Dr. Shepard.

20 This is one of the reasons I am glad we have
21 an advisory committee to take a look at these reports
22 as they come in. I would like for you to do that and
23 get back to me in one month through Dr. Shepard.

24 Secondly, I would like to acknowledge the
25 participation of veteran groups in this advisory group

1 and also that I understand the American Legion is
2 going to be surveying its members to evaluate their
3 evaluation of the VA and how we are handling Agent
4 Orange, how we are examining veterans who claim Agent
5 Orange exposure, in other words, our whole response to
6 the issue.

7 Dr. Brick, I would say, we would be most
8 interested in the results of the American Legion's study.

9 That is all I have at this time, Barclay.

10 CHAIRMAN SHEPARD: Thank you very much.

11 I think each member of the Committee has a
12 copy of the study Mr. Cleland has referred to; we will be
13 speaking about it more and we will look forward to your
14 comments.

15 DR. HONCHAR: Dr. Shepard, may I continue with
16 my last question?

17 CHAIRMAN SHEPARD: Surely.

18 DR. HONCHAR: With regard to both the Nitro
19 and the Sauget cross sectional medical surveys you are
20 conducting or have been conducting or are now analyzing,
21 would it be possible for you to briefly summarize what
22 some of the end points are that you are looking at?

23 DR. SUSKIND: With respect to the Nitro
24 study, the end points are numerous. With respect to the
25 Sauget study, it was really a very limited study and had

1 to do with the clinical examination of the dermatological
2 effects, the effects of the pentachlorophenol exposure
3 alone or a mixture of pentachlorophenol exposure with
4 the ortho and parachlorophenol.

5 There were just a very few people who were
6 just exposed to ortho and parachlorophenol.

7 We were largely looking at the dermatological
8 effects by examination. We did have an opportunity to
9 do a large number of laboratory studies which would
10 indicate abnormal effects, adverse effects, if they could
11 be related to the exposure or the degree of exposure to
12 any of the two processes.

13 In the case of pentachlorophenol exposure,
14 it ended in 1978. The ortho and parachlorophenol
15 exposure is still continuing.

16 The small number of ortho and parachlorophenol
17 exposures showed no chloracne.

18 It is difficult to say at this point that the
19 pentachlorophenol exposure in combination with the ortho
20 and parachlorophenol exposures produced any more severe
21 effects or a larger number of effects than did the
22 pentachlorophenol exposure.

23 The end points in the Sauguet study largely are
24 dermatologic manifestations as well as the laboratory
25 abnormalities which may be found in relation to the

1 exposure.

2 Of course, in any study, the interview which
3 includes family history and previous medical history and
4 reproductive history and history of effects on other
5 organ systems besides the skin, in the Sauguet study, the
6 medical records were very good. We could, for example,
7 if there was an interview history of hypertension or
8 cardiovascular disease, we could confirm it by medical
9 records rather easily.

10 It was very interesting to us to find out
11 and to discover how accurate the interview histories were
12 in comparison to the records. The plant had a rather
13 substantial medical insurance program for the whole
14 family of the workers. All of that was reported and we
15 had access to that.

16 Insofar as the end points for the Nitro
17 program, if we have time I can show you a couple of
18 slides of the many end points. They include
19 reproductive, any increased risk for reproductive
20 abnormalities, cardiovascular abnormalities, neurologic
21 and behavioral abnormalities.

22 Some of this is very difficult to do in a
23 relatively short examination. Each of these examinations
24 took four hours. We were there for a couple of weeks.

25 The individuals were examined with an .

1 interview plus the laboratory work and the hands on
2 examination with pulmonary function, nerve velocity
3 and ECGs and so on, which took about four hours.

4 The end points were those things we are
5 concerned about as to increased risk which emerges from
6 previous findings in the literature as well as animal
7 experiment findings, increased risk for cancer, increased
8 risk for hypertension, cardiovascular and coronary disease.

9 The things we were looking for were rather
10 numerous and we felt that is the way it should be.

11 The program for this came essentially out of
12 a meeting at the IARC in January of 1978 in Lyon. It
13 was there the group discussed a common protocol to be
14 used by four studies of industrially exposed groups
15 that needed to be followed in order to determine what
16 the long term effects were.

17 We essentially carried out the protocol which
18 was discussed in Lyon in 1978.

19 DR. HONCHAR: Thank you very much.

20 MR. DeYOUNG: Dr. Suskind, who is sponsoring
21 and funding this research? Is this a Federal program?

22 DR. SUSKIND: We as a Department are largely
23 supported by the NIH, by the Federal Government. We
24 have a center and the faculty of this center are largely
25 supported by Federal funds. To carry out a large study

1 like this, we needed additional support, and the support
2 after a little convincing came from the industry itself.
3 That is to carry out the hands on examination and the
4 travel. It was a very large group and it required a
5 substantial amount of support.

6 Our center grant could not possibly support
7 that kind of study. We did get support from the Monsanto
8 Company for it.

9 The design of that protocol, every aspect
10 of that study is of University of Cincinnati origin.

11 MR. DeYOUNG: Thank you.

12 CHAIRMAN SHEPARD: Are there any further
13 questions on the continental U.S.?

14 DR. KINNARD: Dr. Suskind, I did not get
15 the control group figure referred to for the Nitro,
16 West Virginia study.

17 DR. SUSKIND: The control group was the
18 group that was unexposed, never exposed to the 2,4,5-T
19 process. They were exposed to other things but not to the
20 2,4,5-T process.

21 DR. KINNARD: How carefully were those controls
22 matched with the experimentals? They were matched with
23 what characteristics?

24 DR. SUSKIND: The matching was a very difficult
25 thing to do in that instance because the control group

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1 was composed largely of active workers and a few retirees.
2 The people who were exposed went back to the 1940's and
3 many of those retired or many of those left the company.

4 The exposed group is to some degree an older
5 group that we have no way to avoid, if we wanted to have
6 our control group from the company itself.

7 DR. HONCHAR: I assume you will also compare
8 the exposed to an age-sex adjusted rates?

9 DR. SUSKIND: Yes.

10 DR. HONCHAR: Thank you.

11 CHAIRMAN SHEPARD: Dr. Suskind, I wonder if
12 you would be willing to talk about some of the extra
13 U.S. studies that are going on, for example, Sebaso? Are
14 you prepared to say anything about the progress of
15 that study?

16 DR. SUSKIND: Perhaps a little. I think those
17 of us who were involved very recently in the National
18 Academy of Sciences meeting with the Seveso group
19 found there was some new information but not very
20 remarkable.

21 There were suggestions of reproductive
22 problems but only suggestions. There was no doubt there
23 was chloracne in the children who were originally exposed
24 to the effluents from that accident. There were many
25 more cases especially children who went back to the homes

A 1 and zone which had been declared off limits. This zone
2 had still to be cleaned up. I think Dr. Murphy knows
3 more about this than I do. Perhaps he would like to
4 comment.

5 The delay in the emergence of chloracne was
6 simply because there was a delay in exposure of those
7 children to the material which was still around in Zone A,
8 I gather.

9 Perhaps Sheldon might comment on the new
10 information.

11 DR. MURPHY: I think there was as you said
12 suggestions of possible neurologic or neuromuscular
13 effects in some of the exposed population but again
14 this was not strikingly serious. It was determined
15 more from physiological electromonographing studies.

16 As I recall it was a very preliminary report.

17 CHAIRMAN SHEPARD: Is the Seveso study using
18 the same protocol?

19 DR. SUSKIND: No, they are not using the same
20 protocol, not to my knowledge. They are wide ranging
21 in their efforts. The reproductive follow-up is being
22 done by one group and the communicable disease follow-up
23 is being done by another group. The neurobehavioral
24 follow-up is being done by another group. Coordination
25 I gather is a problem there as well.

1 They have had their problems and they are not
2 scientific.

3 MR. DeYOUNG: Dr. Suskind, I would like to hear
4 a little more about the data or the observations that
5 went into the conclusion that there is suggestions of
6 reproductive problems. Can you be more specific?

7 DR. SUSKIND: I am sorry. If I had known
8 we were going to discuss Seveso, I would have brought
9 along some of this information.

10 There is a rather good review of the Seveso
11 data by Bo Homestead in the International Archives of
12 Toxicology. It is called "Prologamena to Seveso." It
13 is a review of all the information the Italian workers
14 have so far accumulated in relationship to other
15 incidents like the Nitro incident and the West German
16 incident and the Phillips dun Far incident and the one
17 at Colite in England.

18 Since we have a charge to discuss the Swedish
19 papers, I think we ought to do that. They are very
20 interesting.

21 CHAIRMAN SHEPARD: Please go ahead.

22 DR. SUSKIND: There are really four papers
23 from Sweden and one from Germany. The first one is a
24 follow-up by Olif Axelson on the 348 railroad workers.
25 This is a straight forward epidemiologic study. The

1 follow-up is what happened since they were last reviewed
2 in 1973, I believe.

3 This is a group that was exposed between 1957
4 and 1972 to three amino 124 triazol and to several of
5 the phenoxy acids.

6 I think you can take the information at face
7 value but I think you have to be careful about
8 interpretation because of the small number of tumors
9 in each category, whether they are lung tumors or
10 stomach tumors. There are usually one or two in the
11 exposed group.

12 The total number of deaths was lower than
13 expected and this is regarded as the healthy worker
14 effect. I am not sure that concept applies to all types
15 of industrial populations. I am not even sure it
16 applies to this.

17 The comment is made by Dr. Axelson that this
18 lower death rate is probably due to the healthy worker
19 effect.

20 The total number of tumor deaths at an SMR
21 of 1.4, 17 vs. 11.85.

22 Those who were exposed to the three amino
23 triazol had as I recall two lung tumors but no stomach
24 tumors. Those exposed to phenoxy acids alone had one
25 stomach tumor and no lung tumors. In those who were

1 exposed to both, there was one stomach tumor and one
2 lung tumor. What do you do with data like that? Can you
3 conclude if you relate that one tumor to what is expected
4 and the expected is 0.32, you get an SMR of 3.1. Is
5 that significant?

6 I think there is a suggestion of some
7 relationship. I would hate to say this is conclusive
8 based on the minimal numbers of tumors in any category.

9 If you look at the total number of tumors
10 that is what did these people have, they had any tumor
11 you could think of. The interest was focused on the
12 stomach and lung but there were an enormous number of
13 other kinds of tumors.

14 You could not relate the exposure to any
15 specific type of tumor and that is another problem.

16 I think you have to take it at face value.
17 Among these railroad workers there were 17 that died
18 of cancer and there was no indication that there was
19 any higher risk for one type of cancer then there was
20 for another.

21 Perhaps others would like to comment. Dr. Gross?

22 DR. GROSS: Was there any attempt made to
23 combine tumors at different sites and look at
24 combinations of tumors and different organ systems?

25 DR. SUSKIND: You mean combinations of tumors

1 or combinations of exposures?

2 DR. GROSS: Combination of tumors at different
3 sites, tumors that may be related.

4 DR. SUSKIND: I do not think so.

5 DR. GROSS: One problem is that if the
6 diagnosis is made in sufficient specific detail, any
7 kind of tumor would be unlike any other kind of tumor.
8 There are certain natural relationships, pathological,
9 and one can think of tumors of the lymphoreticular
10 system as a group rather than specific.

11 One can talk about tumors of the gastrine
12 intestinal system as a whole.

13 You speak of a great spectrum of tumors in
14 this population. The question is what attempt was made
15 to group these tumors into some logical classification.

16 DR. SUSKIND: I do not think there was. As
17 I read it, they have a laundry list of tumors in
18 relationship to what was regarded as a specific exposure
19 or mixed exposure.

20 The other problem with this study and I will
21 have to tell you Dr. Axelson is a good friend of ours
22 and he visited with us and asked us to comment on this
23 and these are railroad workers from all over Sweden just
24 like any other working group.

25 They may have different life styles than other

1 workers. There is no indication here that they did any
2 thorough histories of use of cigarettes, alcohol, and I
3 gather if they are like other people in that country,
4 there is a substantial use of alcohol. Many of them
5 still smoke.

6 Whether or not this group smoked more heavily
7 than the expected group, I do not know.

8 Those factors are treated rather casually.
9 There was a statement "The railroad workers smoke, the
10 frequency of smoking is about the same or the same as
11 the rest of the Swedish population." I think no attempt
12 was made to really determine whether that was so or
13 whether these people had any family histories of cancer
14 which were different from the rest of the population.

15 None of that is in this information.

16 CHAIRMAN SHEPARD: The Committee has had the
17 opportunity to review these studies. I wonder if any
18 other members of the Committee would like to comment on
19 the studies.

20 Dr. Murphy?

21 DR. MURPHY: I am not an epidemiologist. I
22 was concerned also about the few numbers of tumors here
23 and there were three stomach cancer tumors and not one.

24 Depending on which time you look at it, if you
25 look at it in ten years induction latency period,

1 they were only looking at two, in connection strictly
2 with the phenoxy acids.

3 Giving risk ratios, again, depending on
4 whether you look at it for the total group and in this
5 case you have 3.3 which does not seem so high to 7.7
6 dealing with these very small numbers.

7 As I understand these articles, very nearly
8 the same risk ratios came out whether they looked at
9 counties in northern Sweden, southern Sweden and then
10 in one other study which I do not recall what the workers
11 were. They were not railroad workers.

12 I quite frankly being a non-epidemiologist
13 was quite struck by these things. I was concerned about
14 this.

15 DR. SUSKIND: Are you talking about the case
16 control studies or the railroad workers?

17 DR. MURPHY: I may be mixing apples and
18 oranges here.

19 DR. SUSKIND: I am talking about one study. I
20 think the case control studies have to be discussed
21 differently.

22 DR. MURPHY: I am grouping the studies.

23 DR. SUSKIND: I think we ought to stick with
24 the railroad workers study just like I stuck to the Nitro
25 study. I think there what they did I thought was the best

1 they could probably do under the circumstances.

2 How much information they were able to get
3 bears on the numbers of tumors is what I am concerned
4 about. Here, too, in that railroad worker group, there
5 was one lung tumor in the amitro group and two lung
6 tumors in the phenoxy herbicide group, two stomach
7 tumors.

8 In the combined group there was another stomach
9 tumor.

10 DR. KEARNEY: Mr. Chairman, I know you
11 probably want to get on. I would like to ask one
12 question.

13 These studies have been discussed all throughout
14 Government as you know, up and down every committee that
15 is doing something on this issue has discussed these
16 reports. It was discussed in the White House Interagency.

17 Could you give us a simple summary of what
18 these studies tell us? The reason you were asked to
19 assist us in the Advisory Committee is we did not have
20 an epidemiologist on the Panel.

21 DR. SUSKIND: You still do not.

22 DR. KEARNEY: Maybe this is the closest we
23 are going to get.

24 Could you give us a simple summary of what
25 this tells us? What is the validity of this data in

1 helping us make judgments about the effect of phenoxies
2 on cancer?

3 DR. SUSKIND: Are you talking about the
4 railroad workers study or all four papers? I assume
5 you are talking about all four papers.

6 DR. KEARNEY: Yes.

7 DR. SUSKIND: I think that is why we are
8 discussing it. Is this a red flag and whether or not
9 you have great confidence or less than that in the case
10 control method which is a very interesting method.
11 Some epidemiologists think it is the greatest thing
12 since the wheel. Others feel it only provides
13 association but not causation.

14 Even if it provides association, as I think
15 the Hardell and Sandstrom studies do and the Eriksson
16 studies do, we should be alerted. I think that is
17 their importance.

18 In this country we have not conducted case
19 control studies with respect to tumors and as they are
20 related to exposure to phenoxy herbicides and maybe we
21 should.

22 It may be a little easier to do in Sweden
23 because it is a small country and they have a national
24 registry which provides them with their controls. It
25 is easy to match the tumor cases with the controls because

1 of the registry. It would not be so very easy in the
2 United States. It would depend on the state.

3 DR. LINGEMAN: It could be done through the
4 AFIP. We will be talking about this later. The AFIP
5 have a large number of tumors of types that are
6 pathologically confirmed.

7 DR. SUSKIND: These are mostly from the cases
8 that have died largely.

9
10 DR. BRICK: I am aware of the small number of
11 tumors. How does this compare with the Swedish incidence
12 of cancer of the stomach or these other cancers
13 throughout the Swedish population?

14 We know that in Sweden, cancer of the stomach
15 is more common than it is in this country. Does this
16 mean that this group of railroad workers had an incidence
17 higher than the average population whatever their
18 population?

19 DR. SUSKIND: Dr. Brick, in this group of 348
20 railroad workers, those who were exposed to phenoxy
21 herbicides alone, there was one cancer of the stomach
22 and the expected rate is 0.32. SMR is 3.1.

23 Can you make a decision on the basis of one
24 case? That is what I am getting at.

25 I think it is still something that suggests

1 association and it should be followed up. The studies
2 that really suggest association are the case control
3 studies with respect to soft tissue sarcomas and lymphomas,
4 both Hodgkin's and non-Hodgkin's lymphomas.

5 It is suggested. I think you need what else
6 these people were exposed to. We have a problem of
7 getting to know how much they were exposed to, the
8 phenoxy herbicides or chlorophenols, how they were
9 exposed and what else they were exposed to.

10 That is not available except descriptively
11 but not quantitatively.

12 I still think with these four studies on
13 hand, that we have the responsibility of conducting
14 similar studies within the United States. We are
15 certainly concerned about the association and whether or
16 not we believe the case control method is good or not. I
17 happen to think it is an excellent way of studying
18 problems as they may be associated with factors,
19 environmental factors, metabolic factors, whatever.

20 DR. SHEPARD: I wonder if I could ask
21 Dr. Rogan to comment? He has reviewed these articles
22 and has been involved in the Scientific Panel of the
23 Interagency Work Group.

24 Dr. Rogan, do you have any additional
25 observations you would like to make? Do you know of any

1 similar studies that could be used for a basic
2 comparison to these studies?

3 DR. ROGAN: When we are talking about the
4 railroad study we are talking about what is called a
5 follow-up study that can be done in real time where you
6 identify a group of people and follow them forward over
7 years to see what happens to them, or it can be done
8 in paper time where you identify a cohort of records
9 starting at some time in the past and look now at causes
10 of death.

11 This is a sort of mixture of those. Three
12 hundred and forty-eight (348) people in such a study is
13 a rather small number. The historic Dow and Hill study
14 of smoking and lung cancer with 34,000 British physicians
15 was controversial.

16 I think Dr. Suskind is right. A cohort study
17 of mortality is a rare event on 348 people and it
18 constitutes essentially a clinical observation.

19 Stomach cancer goes along with some of the
20 anhydrousis syndromes and thus is familial and that
21 should really be addressed in a study of stomach cancer
22 and was not in this.

23 We have a clinical hint that something might
24 be going on with stomach cancer in terms of chemical
25 exposure or that families tend to work in railroad

1 workers union or tend to take the same jobs and those same
2 families are the ones that get stomach cancer.

3 The reason for the doubts about case control
4 methodology without getting at all technical is simply
5 that you must ascertain exposure after the illness of
6 interest has occurred, thus instead of identifying a
7 population of people and following them forward in time,
8 you identify a set of cases and inquire among them what
9 their exposures historically might have been.

10 If there is a link in the minds of the cases
11 that such exposures might have been bad for them, they
12 may remember and thus report to you selectively that
13 such exposure did take place with a greater frequency
14 than controls who do not have the particular illness in
15 question and thus may not be pressed to remember.

16 The enormous strength of control case studies
17 is you can take relatively rare diseases and gather a
18 great deal of information about them in a relatively
19 short time at relatively little expense. For some of
20 the major human carcinogens, that is the best role. For
21 instance, the first major clue that something was going
22 on came from case control studies.

23 The remaining problem with the three case
24 control studies is they are essentially all from the
25 same group. If there is some kind of bias it is not

1 obvious from the reports that exist and the instruments
2 used by that group such that it selectively gathers
3 information from cases on exposure to these agents and
4 then we are stuck because we do not have external
5 validation, that is, a validation of the same exposure
6 history in the hands of another group.

7 Dr. Suskind mentioned other factors that might
8 go along with these sorts of tumors and thus might
9 compound the relationship, that is some other factor that
10 you did not ask about that is in fact responsible.

11 There are to my knowledge no other strong
12 factors for mycetoma tumors and the only factor I am
13 aware of for Hodgkin's and non-Hodgkin's lymphoma is
14 dilantin and that is kind of suspect. Presumably one
15 could ask about dilantin.

16 Other exposures do not seem to me all that
17 relevant in terms of a relative risk of six or seven. It
18 is hard to build that into a study. You can do it but
19 it is hard to build a bias into a study that gives you a
20 six or a seven.

21 In this case what the six or seven would be
22 is the cases report exposure about six times more
23 frequently than the controls and through some
24 statistical method that comes out to an odds ratio,
25 relative risk sort of number.

1 I am left with three studies from a group
2 essentially, although the authors change, using the same
3 instrument presumably which is unvaluable from the papers
4 which may or may not have something in it that leads
5 automatically to that conclusion.

6 One wonders, for instance, how many other
7 tumor types they tried and did not report on.

8 The follow-up study which is to be essentially
9 a clinical observation because it is so small for a
10 follow-up study, there might be something there.

11 I agree with Dr. Suskind that it calls for,
12 as did DES, as did smoking and lung cancer, as did any
13 other occupational and environmental carcinogen,
14 independent observations in a different population,
15 using a different instrument in the hands of other
16 investigators.

17 CHAIRMAN SHEPARD: Thank you.

18 DR. SUSKIND: Dr. Rogan, when you say the
19 same group, you are talking about Sweden?

20 DR. ROGAN: Yes.

21 DR. SUSKIND: Except they were populations
22 from different hospitals. The soft tissue tumors were
23 different people and different people from a different
24 area of the country. We do not know about their
25 mobility so we have no idea how long they lived or worked

1 in the southern counties in Sweden as compared to the
2 central or north central province.

3 You are concerned that it was only done with
4 a Swedish population. Is that correct?

5 DR. ROGAN: I am concerned that it was done
6 by the same investigators. I think you have to evaluate
7 for possible bias introduced by the investigators,
8 certainly unconsciously, not purposely. You would like
9 to be able to evaluate the validity of their observations
10 from studies in different populations done by different
11 investigators.

12 CHAIRMAN SHEPARD: Ms. Patton has just handed
13 me a note of interest. Dr. Hardell, the principal
14 investigator of the Swedish case control studies will be
15 testifying before the EPA on September 8th and 9th. She
16 thinks that is a pretty firm schedule but it may change.

17 I think it will be interesting to see what
18 Dr. Hardell has to say.

19 Dr. Axelson, as many of you know, has already
20 testified.

21 MR. DeYOUNG: This is new information in a
22 sense. We finally have a scientific study speaking from
23 a layman's point of view which if it is not conclusive
24 proof that we have heard so much about, at least it is
25 some association between certain cancers and exposure to

1 phenoxies.

2 Let me pose an extreme case in the hopes
3 objections to the extreme case, if any, will yield some
4 light on what we still have to determine.

5 The extreme case I would propose is we go
6 on record as combining two factors, the association found
7 in these Swedish studies with the mandate the VA
8 currently has and has always had, to find reasonable
9 doubt in favor of the veteran and that we recommend
10 at this point for certain cancers that have been studied
11 and associated, the VA would have an automatic finding
12 of service connection for a Vietnam veteran for those
13 carcinomas.

14 If something is wrong with that, what is
15 wrong with it?

16 DR. SUSKIND: What you are now saying is there
17 is more than association. It is causal. I do not think
18 anybody here is prepared to say that.

19 DR. BRICK: What about reasonable doubt? Are
20 you aware of what adjudication the Veterans Administration
21 is?

22 CHAIRMAN SHEPARD: I understand it is
23 horrendous.

24 DR. BRICK: We are talking about the
25 veteran's point of view, reasonable doubt. Would this

1 association lend itself to credence if you say this is
2 reasonable doubt, that such an association existed
3 and the veteran was exposed in Vietnam and now has
4 cancer of the stomach?

5 DR. SUSKIND: Judging from the data from
6 Sweden, whether it is the railroad workers data or the
7 case control studies, you could not even go to the point
8 where you could say there is a reasonable doubt.

9 DR. GROSS: Would it not be true to say that
10 no epidemiologic study no matter how good can ever
11 establish an cause and effect relationship, it is always
12 association, is it not?

13 DR. SUSKIND: Not really. I think cigarette
14 smoking and DES, you have both epidemiologic evidence
15 as well as additional toxicologic evidence.

16 DR. GROSS: Does toxicologic evidence
17 establish a cause and effect relationship?

18 DR. SUSKIND: In the model system you use,
19 certainly.

20 DR. HONCHAR: I think there is an important
21 point to be made which is despite the strong evidence
22 associating cigarette smoking and lung cancer, we cannot
23 then take the next step and say based on that information
24 that all cases of lung cancer in a smoker are caused by
25 cigarette smoke.

1 DR. SUSKIND: Because there are non-smoking⁶⁹.
2 lung cancers.

3 DR. HONCHAR: Yes.

4 DR. SUSKIND: We are not considering the
5 side stream exposure.

6 CHAIRMAN SHEPARD: At the risk of interrupting
7 important discussion, I think we are going to have to
8 move along and cover some other areas that I think are
9 very important.

10 DR. MURPHY: The issue of lung cancer was
11 just brought up. What would be a reasonable doubt
12 situation there? Would you conclude someone with a
13 history of smoking, let's assume smoking was a service
14 connected activity, would you assume there was reasonable
15 doubt in a case like that?

16 DR. BRICK: It would be allowed. You would
17 not have to use reasonable doubt. I think the evidence
18 on tobacco smoking and lung cancer is the guy who smokes
19 for 30 years, three packs a day and he gets lung cancer,
20 who around this table is going to dispute the lung cancer
21 even without reasonable doubt may well have been related
22 to smoking?

23 DR. MURPHY: Even in the Swedish studies
24 regardless of how weak that evidence is or how strong
25 you may consider it, there are limitations to that in

1 that they do have requirements for duration of exposure
2 to be included as an exposure group. Am I correct?

3 DR. ROGAN: Yes.

4 DR. MURPHY: The latency period between the
5 time of first exposure and appearance and when the
6 analysis is done is another consideration.

7 CHAIRMAN SHEPARD: Let's go to the discussion
8 on veteran attitudes. Dr. Brick?

9 REPORT ON VETERANS ATTITUDES BY DR. BRICK

10 DR. BRICK: The American Legion is trying to
11 conduct among its members, 2.5 million of them, a study
12 as to how they perceive the Veterans Administration
13 with reference to Agent Orange. There has been wide
14 interest among veterans because of the adjudication
15 problems that have arisen.

16 There is a lot of emotionalism about this
17 subject as all of us in this work know.

18 There is a bill before Congress. I think it
19 is before Senator Cranston's Committee. It would take the
20 burden of proof of exposure to Agent Orange off the back
21 of the veteran. Under the present circumstances, the
22 Adjudication Boards, Rating Boards, are wanting to have
23 some proof that the specific veteran was exposed to
24 Agent Orange.

25 That proof is not easy to get. All of you know

1 the problem with paperwork in the Government and trying
2 to get it out of the Defense Department and some of that
3 they do not have. They do not have the data, they do not
4 have the documentation.

5 This bill would say that a veteran who has
6 been in Vietnam, if he comes up with some complaint, some
7 disease, then it has to be adjudicated on the question
8 of whether this disease might be related to the exposure
9 with resolution of reasonable doubt in favor of the
10 veteran.

11 We are going to come up with that resolution
12 of reasonable doubt. I am sure the epidemiologists do not
13 like that phrase particularly because it could be
14 interpreted in many ways.

15 The American Legion is dedicated to get the
16 best scientific evidence we can with reference to the
17 problems just as the Veterans Administration is.

18 I think the fact that in this Advisory
19 Committee there are the group of diverse talents that we
20 have seen here this morning discussing these scientific
21 matters in a very unbiased fashion indicates that the
22 Veterans Administration is doing as much as it can.

23 Some of the testimony given before this
24 Subcommittee in the Senate was by a Dr. Epstein whom I
25 do not personally know.

1 CHAIRMAN SHEPARD: Excuse me, Dr. Brick. It
2 was the House Veterans Affairs Committee. The hearings
3 were held on July 22nd.

4 DR. BRICK: Yes. Dr. Epstein reviewed these
5 studies. He came out with the same problems all of you
6 have as to the statistical validity of these studies.

7 He pointed as you did, Dr. Suskind, that
8 there apparently is an association. He had lung cancer
9 which was not played up very much but stomach cancer
10 particularly and also testicular tumors which has not
11 been mentioned here and soft tissue sarcomas.

12 One of our members just asked should not
13 certain diseases be given service connection by
14 presumption such as soft tissue sarcomas.

15 I do not think there would be any argument
16 about that because this is a rare tumor. Hodgkin's
17 and non-Hodgkin's lymphoma is a different ballgame. I
18 do not know what the data is on that. I would leave that
19 to the people in the field to decide whether there is
enough data with reference to this.

21 I think I referred a case to you not too long
22 ago, Dr. Shepard, which is being adjudicated before the
23 Board of Veterans Appeals on one of these non-Hodgkin's
24 lymphomas and the allegation that this Vietnam veteran
25 was exposed to Agent Orange and is there a causal

1 relationship again with resolution of reasonable doubt.

2 The adjudication people in the Veterans
3 Administration are very aware of the mandate they have
4 been given by Congress to give reasonable doubt to the
5 veteran.

6 Again we come back to these associations and
7 unless the Veterans Administration does something
8 positive and it is going to be Congress that is going
9 to do it in a bill that is proposed on the hill, I think
10 the veterans in general are not going to be very happy
11 with the outcome of the work of this committee.

12 At the last meeting, Mr. Chairman, I wondered
13 and I again wonder whether this is the proper body to
14 make such judgments. What is going to happen knowing the
15 attitudes of the veterans is that if the Veterans
16 Administration finds and Max Cleland just told us about
17 this report that was in the Saturday edition of the
18 Washington Post that there was no relationship in these
19 animal studies between exposure and birth defects, the
20 Veterans Administration comes out with a negative report
21 which may be the case scientifically.

22 Many of the veterans are going to say, there
23 is a conflict of interest. The Veterans Administration
24 is deciding that, let's have an impartial body decide it.

25 I suggested the National Institute of Medicine

1 of the National Academy of Sciences as the appropriate
2 governmental agency to make a decision. I think it would
3 be accepted more readily by the scientific community and
4 I also think it would be more readily accepted by the
5 veterans.

6 We have this Advisory Committee. We are going
7 to have to face up to the problem in this Advisory
8 Committee of coming out and saying we should give
9 service connection to individuals with let's say soft
10 tissue sarcomas.

11 Dr. Epstein in his testimony also pointed out
12 that some of the individuals exposed did not have
13 chloracne. Chloracne has been used as the synacronon
14 of diagnosis of exposure to Agent Orange.

15 He pointed out that there is a multi-system
16 disease with a good many symptoms, nausea, vomiting,
17 weakness, fatigue, et cetera, that many of these
18 individuals exposed had and that we do not know all of
19 the chronic effects of this problem.

20 From a strictly scientific point of view, it
21 might be of great interest twenty years from now when
22 the Vietnam age group gets up into the 50's and 60's to
23 see whether the incidence of cancer of the stomach, for
24 instance, which is a declining disease in this country
25 at the present time, shows a marked increase in that

1 group. That is going to be twenty or thirty years away
2 and that is not going to help the problem that the
3 Veterans Administration has now in adjudication.

4 I think we all have to keep in mind this
5 problem of adjudication when we try to make judgments
6 about the association of exposure to Agent Orange and
7 the diseases the veterans present to the Veterans
8 Administration.

9 Thank you.

10 CHAIRMAN SHEPARD: Thank you very much,
11 Dr. Brick.

12 I think one of the problems, and I was there
13 for the testimony, that the process that has been used
14 in adjudicating claims would not apply in its present
15 form to a rather vague disease entity, such as this
16 multi-system disease or a broad group of illnesses.

17 I think it is a nebulous task to make these
18 associations. I think we must somehow address the issue
19 or separate the issue of cause and effect relationship
20 between Agent Orange and any disease, complex or system,
21 from service connection.

22 As I understand it, the VA does not require
23 any kind of a demonstration of cause and effect. It is
24 simply some establishment of disease arising from
25 military service regardless of cause.

1 I would like to hear Ron speak about some of
2 the perceptions of Vietnam veterans regarding the progress
3 of our registry.

4 DR. GROSS: If I may follow-up on something,
5 I was very much impressed by the question and I was
6 impressed by the NDP report.

7 I do not know if Dr. Murphy would second me
8 in this, but having had long experience in the valuation
9 of reproductive studies such as were carried on out
10 there and also with the varied abilities of the people
11 to analyze data like that, I would urge you, sir, to
12 consider the possibility of engaging an outstanding
13 analyst in this area to give us the best possible
14 analysis of the results.

15 If we have no such talent ourselves, perhaps
16 we should go out on contract, a short contract. That
17 would be the best way to have an evaluation of the
18 conclusions that the NDP reached.

19 CHAIRMAN SHEPARD: That is a good suggestion.
20 Thank you. Ron?

21 REPORT ON VETERAN ATTITUDES BY MR. DeYOUNG

22 MR. DeYOUNG: As a background to what I can
23 say about veteran attitudes, my own connection has been
24 rather heavy over the last three years with veterans who
25 are not the satisfied customers of the VA but rather

1 the disillusioned and disgruntled people who have not
2 been able to get the system to function.

3 Much of what I have heard if not all of what
4 I have heard from veterans is extremely negative. It
5 centers around a number of different phenomenon, none of
6 which we are strangers to if we have worked in
7 Washington at all; the size of the bureaucracy, the
8 number of papers involved, the time in which it takes
9 to get anything done.

10 If I can single one negative attitude out
11 head and shoulders above the others, impersonalization.
12 I would suggest insofar as we can alléviante this
13 problem, we have done the veteran an enormous service.

14 There is something which I am not sure of
15 the status of internally right now but which has been
16 started within VA in response to this statement a number
17 of months ago.

18 One of our associates in Chicago suggested
19 the basic problem with VA service was it was always a
20 different person you saw when you came in. There was no
21 human follow-up to the thing, although there may be
22 paper kept up. There was no feeling on the part of the
23 veteran of progress because he had to start over each
24 time he came in, essentially.

25 The Chicago man's suggestion was that a

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1 TRIOSH team of sorts be established at each VA hospital
2 so that it was the same doctor each time that the
3 veteran came in for an exam. Insofar as that is
4 functionally possible, it is my understanding that VA
5 is moving in that direction.

6 I see that as a big advance. That certainly
7 will go a long ways towards building trust on the part
8 of the veteran because he has a human contact and not
9 just a blank name, face, intern, whatever.

10 You have to remember in talking about Vietnam
11 veterans attitudes that any generalization is false
12 and this is to a limited extent, we are dealing with
13 people who went over patriotically and came back
14 disgruntled for one reason or the other.

15 That disillusionment with the war itself, with
16 the military, with society at the time has lapsed over
17 and by extension has fallen on the Veterans Administration.
18 In many ways I pity the people at VA who have to work
19 with this disgruntled veteran.

20 I can come at them as a peer but maybe you
21 people cannot insofar as there are Vietnam veterans
22 working for the organization.

23 Insofar as possible, please attempt to
24 involve the Vietnam veterans within the VA directly with
25 the veteran in the street; that bond that exists there

1 cannot be achieved any other way.

2 I have been getting less reports of problems
3 lately. I do not know if that reflects the fact that
4 my phone number has been changed or the fact that
5 veterans are not complaining so much any more. If that
6 is the case, then we can assume things are working better
7 and from informal reports I have been getting from our
8 people, it is better on paper.

9 There are isolated problems where a vet goes
10 in and an appointment is not made out for him. This is
11 nothing unusual. These are the kinds of things that
12 the VA is coping with ordinarily.

13 I think there has been an enormous growth in
14 the VA's procedures for handling Vietnam veterans who
15 request an Agent Orange exam and insofar as the paper
16 procedures can be carried out system-wide, I think you
17 are getting some success.

18 CHAIRMAN SHEPARD: Thank you very much, Tom.
19 Are there any questions?

20 (No response.)

21 CHAIRMAN SHEPARD: I would like to call on
22 Mr. Charles Thompson from DAV.

23 REPORT ON VETERAN ATTITUDES BY MR. THOMPSON

24 MR. THOMPSON: Thank you, Dr. Shepard.

25 As I indicated at the last meeting, this is

1 obviously a very complex subject, not easily understood
2 by many of the Vietnam veterans.

3 As Ron indicated, we have many Vietnam
4 veterans who went over to Vietnam and questioned the
5 military leadership and the type of war that was being
6 fought. They now come home and are starting to question
7 the confidence of our Government officials.

8 They were forgotten and scorned. Many of them
9 felt this way. Now they feel they are being ignored on
10 the subject of Agent Orange.

11 I have to agree with Ron on the impersonali-
12 zation. I think it is improving. I think the
13 Administration is taking a more responsible and sensible
14 approach to the subject.

15 I think we need to continue this. We need to
16 be more informative and more consistent in the type of
17 information that is put out to the Vietnam veterans.

18 I think the new brochure just released is
19 of great help.

20 We in the DAV as I indicated at the last
21 meeting, when we come in contact with veterans writing
22 in or calling in, we try to give them the whole gambit,
23 not only the adjudication process, the examination
24 process at the outpatient clinics or VA Hospitals but
25 exactly what they are going to face when they file their

1 claim for benefits.

2 I would just summarize by saying that I
3 believe it is incumbent upon this Advisory Committee to
4 maintain its aggressive approach.

5 CHAIRMAN SHEPARD: Thank you. Are there
6 any questions or comments?

7 DR. MURPHY: I recently was asked to talk to
8 a group of people, some of whom were Vietnam veterans
9 and some of whom were education or various advisory
10 groups of Vietnam veterans in South Texas.

11 A couple things came up at that time that I
12 would like to ask about or see what progress has been
13 achieved.

14 In the registry, what interest do you have
15 of getting Vietnam veterans to go in who do not have a
16 complaint, either who had exposure but no complaint or
17 someone who has not had exposure?

18 Are you interested in getting these veterans in?

19 CHAIRMAN SHEPARD: Very definitely. It
20 certainly is known to all our medical facilities. We
21 hope that through a number of different avenues we will
22 be able to reach veterans and encourage them if they have
23 a concern about exposure. We do not suggest they need
24 to have any physical findings or any demonstrable ill
25 effect.

1 We want veterans to enroll in the registry.
2 This will give us a number of answers. It will give us
3 a hint as to the magnitude of the problem as is perceived
4 by the veteran population. It will give us an idea as
5 to where these people are, what kinds of problems they
6 have if they are experiencing problems but even if they
7 are concerned.

8 For example, the whole issue of birth defects
9 has caused a high level of anxiety. We get phone calls
10 every day from veterans individually, collectively,
11 through organizations, requesting advice as to whether
12 a pregnant wife should have an abortion or whether the
13 veteran should have a vasectomy because they have heard
14 all these horror stories about birth defects.

15 We are encouraged by the male mouse study
16 that at least insofar as animal work can be a signal,
17 that there is not at least in this study a suggestion of
18 increased infertility, birth defects, spontaneous
19 abortions.

20 I think this kind of study is going to go a
21 long way to allay the fears of those veterans who have
22 raised this concern.

23 To answer your question, yes, we do want all
24 veterans who have any kind of a concern to get enrolled
25 in the registry. This way we can accumulate the data.

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1 DR. MURPHY: I would think at least some
2 cohorts, if that is the proper term, of veterans who
3 do not have complaints and maybe do not have an exposure
4 would be ultimately useful in your analysis of the data
5 of those who do have complaints.

6 I think you have answered my question. The
7 other thought is we happen to have in Houston at the
8 Veterans Hospital there a very interesting man named
9 Dr. George Cromwell. He also happens to know that I am
10 on this Committee and has referred several individual
11 veterans to me.

12 I have had a number of calls from veterans
13 who for one reason or another do not want to go to the
14 VA and have gone to private physicians and this issue of
15 impersonalization almost seems as much a problem there
16 in that I get the impression that there is a fair
17 population of physicians in the country who do not know
18 what Agent Orange is.

19 They might know what dioxin is and they might
20 not.

21 What effort has the VA done through the
22 medical associations to try and alert physicians, give
23 them some education? I know medical schools have not
24 in the past and probably still are not doing a great job
25 of instruction on chemical induced disease.

1 CHAIRMAN SHEPARD: That is a very good
2 question, Dr. Murphy. It is one we are very concerned
3 about. In the press of other duties, I think we have
4 not been as aggressive as we should and I hope will be
5 in terms of informing the general medical public in this
6 matter.

7 I think it is time for the VA to come out
8 with some informational material for the medical
9 provider at large.

10 One of the things we are doing for our own
11 medical provider is an educational film relating to
12 chloracne. I hope that will be a very substantial piece
13 of training material.

14 We are also developing or we are now in the
15 final stages of developing educational material for the
16 veteran about the whole issue of Agent Orange. It is a
17 kind of broadening out of what is in the pamphlet. This
18 will be an audiovisual tape which will be available I
19 hope within the next couple of months.

20 A follow-up to that will be a similar kind of
21 educational audiovisual tape aimed at the physician
22 community outlining some of the chemical, toxicological
23 problems.

24 DR. MURPHY: Has anything gone into such
25 publications as the AMA Journals, the Physicians'

1 newsletters that go out from these associations? Would
2 it be difficult to get something in those?

3 CHAIRMAN SHEPARD: That is a very good
4 suggestion; not to my knowledge from the VA. I think the
5 time is now here for us to start working along those lines.

6 MR. DeYOUNG: In response to that, there have
7 been several attempts from private physicians who have
8 treated Vietnam veterans and Gilbert Bogan comes to
9 mind from Illinois, one of our unofficial doctors from
10 the Midwest.

11 We have had a small group of physicians in
12 the Midwest and Chicago area who have been interested in
13 tracking these veterans, sometimes on parallel tracks
14 and some veterans are not going to the VA at all but
15 rather to these private physicians.

16 Dr. Bogan published a letter in the JAMA of
17 November last Fall which described his findings in a
18 case of 74 Vietnam veterans.

19 The Veterans Task Force on Agent Orange is
20 also in the process of trying to formulize the currently
21 informal physicians' registry which we have. I would
22 suggest any physicians who fit this description might
23 want to be involved.

24 The National Veterans Task Force on Agent
25 Orange is developing a referral network for Vietnam

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1 veterans who believe they were exposed to Agent Orange
2 while serving in the military who have various serious
3 problems.

4 We are interested in receiving the names of
5 sensitive, qualified physicians who might be interested
6 in providing treatment.

7 Expertise in the following areas would be
8 helpful; dermatology; oncology; genetic counseling;
9 internal medicine; psychiatry; psychology and endocrinology.

10 This is being shepherded by Ms. Ruth M. Schaffer
11 who can be contacted at our office in St. Louis. This is
12 in conjunction with City University in New York.

13 CHAIRMAN SHEPARD: Dr. Suskind?

14 DR. SUSKIND: I would like to underscore the
15 comments made by Mr. DeYoung and Mr. Thompson about
16 the responsiveness of the local veterans medical units
17 to requests or complaints or whatever the veteran brings
18 in, with the claim that he was exposed to Agent Orange.

19 I also think it is an excellent idea to have
20 a separate unit, a medical unit within the Veterans
21 Hospital which does all of those examinations. Those are
22 the experts, will be, should be. With the number of
23 veterans that are likely to take advantage of this, it
24 is terribly important that you have not the general
25 outpatient clinic response, but that you have a specific

1 unit response.

2 I would hope that is being done or will be
3 done.

4 CHAIRMAN SHEPARD: Each one of our medical
5 facilities, all our hospitals and outpatient clinics,
6 have a designated environmental physician. The way that
7 is being implemented and each station may differ, but
8 in the larger centers, the demand on one physician
9 probably exceeds his capabilities to perform all the
10 examinations but he has the responsibility of organizing
11 in that facility whatever it takes to develop a
12 responsive, compassionate program.

13 In some of the smaller facilities, I am
14 confident the environmental physician himself is involved
15 with the majority of the hands on contact.

16 DR. SUSKIND: The interest in doing this
17 has obviously increased even from where I sit as not
18 being a member of the Veterans Administration or one of
19 their hospitals.

20 We had any number of requests from Veterans
21 Hospital units over the country to put on programs,
22 educational programs for their physicians, specifically
23 addressed to the diagnostic, the assessment problems
24 of the Vietnam veteran as it relates to Agent Orange.

25 This is only within the last two or three months.

1 The Council on Scientific Affairs of the AMA
2 has just established an advisory committee on toxic
3 substances. One of the issues that has been raised is
4 what should the AMA do in its educational program about
5 Agent Orange.

6 I think one of the things they would like to
7 do is provide a forum for information and discussion
8 of the clinical problems which might arise as a result
9 of Agent Orange.

10 The man who is coordinating that activity is
11 named Wheater. He is an industrial hygienist who is
12 kind of acting as executive secretary of that office.

13 CHAIRMAN SHEPARD: Thank you very much,
14 Dr. Suskind.

15 We are concerned that we get this information
16 out beyond the VA so it will be general information. We
17 are working towards that end.

18 I would like to thank the gentlemen for their
19 comments. We highly endorse your efforts to work with
20 us. We certainly want to increase that relationship
21 and strengthen it.

22 I think we need to move on now. We have some
23 very interesting activities that are either ongoing or to
24 be proposed.

25 We have asked Dr. Rogan to say a word about

1 Dr. Ton-That-Tung's study. Those of you who may not
2 be aware, he is a doctor in North Vietnam who has done
3 a report on birth defects. In a word, maybe, Dr. Rogan,
4 you can summarize your impression of that study.

5 REPORT ON PROFESSOR TON-THAT-TUNG'S LATEST STUDY
6 BY DR. WALTER J. ROGAN

7 DR. ROGAN: Basically this is sort of a three
8 part report; one on a relatively large population,
9 10,000 or so; one on a smaller population, 4,500 and then
10 some reports of outcome of pregnancies among individual
11 former soldiers, some of whom came back from the South
12 and were presumably sprayed or exposed, some of whom
13 never left the North and thus who presumably were not.

14 DR. ERICKSON: May I ask what is the source
15 of these documents that have been distributed to us?

16 CHAIRMAN SHEPARD: As I understand it, this
17 was an article which was sent to somebody in Wisconsin
18 with a handwritten note from Dr. Tung himself indicating
19 he was in hopes that his article would be published in
20 the New England Journal. To my knowledge, his article
21 has not been published.

22 What we are referring to is a manuscript which
23 was written in French and translated by a non-physician
24 and perhaps even a non-scientist in Eau Claire, Wisconsin.

25 Some of you have been provided with the

1 original French manuscript. Those of you who have
2 requested that have made a review based on the original
3 manuscript and some of you have the translation which I
4 understand suffers in some degree.

5 DR. ROGAN: Yes, in the literary degree.

6 DR. ERICKSON: What we have presumably is
7 a photocopy of the translation?

8 CHAIRMAN SHEPARD: Presumably. I have no way
9 to verify that.

10 DR. ROGAN: I have the manuscript in two forms
11 in English, one which is presumably an earlier version
12 and it has fewer references and the number of soldiers
13 investigated in the third part is considerably smaller.

14 Working from two translations and my own
15 horrible French, I have tried to figure this out.

16 The first thing I sort of looked for in
17 the evaluation of a possible major teratogenic effect
18 was the so-called signal anomaly, that is the kind of
19 disease or structural malformation that is so unique,
20 so rare, that it is striking and evidence in itself.

21 The classic example is the phocomelia, the
22 limb reduction defects that follow exposure to
23 thalidomide during pregnancy.

24 By my reading, there is no such signal
25 anomaly here. There is nothing that occurs in many, many

1 cases similarly that is very unusual or unheard of outside
2 these populations and would somehow lead you immediately
3 to the conclusion that something strange was happening.

4 Being unable to find such an anomaly, once
5 has to go back to rates, that is you define a population,
6 you establish the number of outcomes of interest that
7 arise from that population and you compare it to some
8 other presumably unexposed group with the idea of drawing
9 an inference about the differences in the rates.

10 A necessary step in drawing such inferences
11 is that the presence of the anomaly structural
12 malformation, whatever, does not in any way affect the
13 likelihood that one will be reported on, in other words,
14 the disease in question itself cannot affect the
15 likelihood that you are going to be counting out of the
16 population since almost always in human studies not
17 everybody is counted and you cannot have a differential
18 coming in.

19 I looked at the idea of trying to calculate
20 rates from the data in this paper. For the first one
21 we have 3,058 births arising from a population of less
22 than 10,000 in four years.

23 Just crudely and arithmetically, that comes
24 out to 400 pregnancies per 1,000 population per year.
25 That is an astounding rate, even in the emerging

1 countries where birth rates are very high and infant
2 mortality is very high, no such rate as 400 was ever
3 approached. Forty is the highest but there may be
4 higher.

5 Somehow births are being ascertained better
6 than population. We know more about babies than we
7 know about people.

8 That makes it very difficult to calculate
9 our rate because I do not know what it is arising from.

10 The list of anomalies allows one to look at
11 the notion of mechanism, that is, one would hope to find
12 anomalies in here that could conceivably result from
13 male exposure, that is perhaps structural anomalies of
14 chromosomes or the so-called signal anomalies like
15 neurofibromatosis or acontemplasia.

16 What one is struck with is the absence of the
17 common defects that we see in this country, Down's
18 syndrome; hypospacias. They are not here. This is
19 a funny collection of anomalies.

20 Anencephaly runs in families, conditional on
21 a mother giving birth to a child with anencephaly, she
22 has about a five percent recurrence rate and given she
23 has had two such children, about 15 percent. This runs
24 in genetic groups, higher in the Scotch Irish. I am not
25 aware that it is higher in Vietnamese.

1 This is a lot of anencephaly. Since I do not
2 know how big it is drawn from, I cannot say how big is
3 "a lot." By the number of births, it should be a much
4 bigger population than it is. I do not know given that
5 whether this is too much anencephaly to say there is a
6 background of anencephaly. It occurs unlike phocomelia.

7 Some of these are consistent with aneuploid
8 babies, that is babies that have the wrong number of
9 chromosomes. Some of them are consistent with the
10 so-called embryonic band effects which are not thought
11 to have an obvious genetic sort of mechanism but rather
12 a physical sort of mechanism that goes along during the
13 pregnancy.

14 The absence defects are very unusual in my
15 experience and I am not really sure what to make of it.

16 The clefts and hairlips are the kinds of
17 anomalies we see in this country. There does not seem
18 to be too many of those given and I do not know what
19 the population is.

20 What I am stuck with is I cannot calculate a
21 rate because I do not know what the number was over. What
22 I can say from the first study is there are among the
23 children of soldiers who have returned from the South
24 some congenital anomalies, whether that is more or less
25 then I would have expected from such a group I cannot tell

1 because I do not know how big the group is. I suspect
2 it is not what is reported in the paper because that is
3 an unheard of fertility rate.

4 Batrachian abdomen, "batrachian" is a French
5 word for frog. I have talked to some people who speak
6 both teritology and French. They are puzzled by that
7 word.

8 There are sort of slang terms in use in this
9 country for some anomalies. The one that came immediately
10 to mind was the prune belly syndrome which is absence
11 of the abdominal musculature. It is an extraordinarily
12 rare anomaly and should not account for the many times
13 that it is present here, even among the so-called control
14 groups.

15 I have looked through my book that talks about
16 and shows pictures of children with structural anomalies.
17 The closest I can come is either it represents anomalies
18 along the line of the diastasis tuinfalliceals which are
19 the ventral hernia anomalies where the abdominal
20 musculature does not close around the umbilical cord or
21 that it represents simply a frog or pot belly, thus, a
22 swollen belly, thus acytees in the baby. This results
23 from perhaps destruction of red cells, perhaps
24 malfunction of the kidneys of the fetus.

25 Again, it is very unusual and is not described

1 in American nurseries. You do not describe as a
2 structural anomaly a pot belly on a child. I am left
3 with that. I cannot get a good answer for that.

4 Both Dr. Erickson and I have cased around
5 trying to find out what that means.

6 I am stuck with the first one. The second
7 one from the smaller group represents a much more
8 reasonable birth rate for a population, down around
9 17 per 1,000.

10 The anencephaly is the anomaly of major
11 interest. The problem we have here is as I said,
12 anencephaly runs in families. Here we have it running
13 in families. It is a rare event to have this number of
14 anomalies in a small number of families but that is
15 where those numbers come from, that is five, fifteen
16 percent come from families that have experienced this.

17 We are not told specifically whether those
18 families are ones with some kind of unusual exposure.
19 In fact, they are not really much characterized at all
20 particularly in terms of other family history of
21 anencephaly.

22 One has difficulty interpreting this because
23 of what exactly is the rate. These are non-independent
24 sorts of observations.

25 The batrachian abdomen appears commonly and

1 I simply do not know its name in English.

2 I have two investigations of soldiers who have
3 returned versus soldiers who were in and stayed. In my
4 original French and in one of my English translations,
5 it is a much smaller number. When I looked at it,
6 I thought how did they find the individual soldiers that
7 they interviewed, was finding them in some way related to
8 the fact that the child was somehow abnormal. If that
9 is the case, again one cannot calculate a rate because
10 the probability of being found by the investigators is
11 altered by the fact of what you are counting so you cannot
12 count it.

13 When I got the second paper which had a
14 larger number, that was sort of born out because they
15 were able to find more and more people as the inquiry
16 went on. We have not enumerated some kind of a
17 population. It said there were one million such people
18 and I counted all of them or a random sample of them and
19 I counted the number who came to my attention.

20 Ancillary to that is some of the numbers that
21 they have here. If you ask American women or women in
22 most developed countries, not age-specific but overall,
23 approximately what their spontaneous abortion-miscarriage
24 rate has been, you will get a number something like
25 15 percent of pregnancies.

1 If you add to that premature deliveries, you
2 will get some number higher. In North Carolina, for
3 instance, the number of children born definitionally
4 premature, that is under 2500 grams at birth, is about
5 8 percent.

6 What we have here is Group A, the soldiers
7 returning from the South married to a Northern woman
8 who give a combined history of both abortions and
9 premature deliveries of 15.3 percent, a low number even
10 given these people are reproducing perhaps at an earlier
11 age.

12 The sterility number I am not sure what to
13 do with because I do not know U.S. population numbers.

14 The unexposed group give a rate of 10.4
15 percent and also give a rate of zero out of 309 birth
16 defects.

17 I think most people in developed countries
18 would call a number of about three percent typical. Zero
19 out of 309 would be considered to be unusual.

20 I have another little bit of evidence that the
21 likelihood of being counted by the study is affected by
22 the fact of an adverse outcome. Since that has happened
23 or appears to have happened, I cannot calculate a rate.

24 What I am stuck with is there does not appear
25 to be the so-called signal anomaly nor an increase in the

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1 group of things that one argues as signal anomalies, that
2 is dominant defects that arise from immutations. Examples
3 are neurofibromatosis and achondroplasia.

4 There does seem to be an unusual amount of
5 anencephaly with some dilution by the fact that there are
6 anencephaly families in this study.

7 Parenthetically the second smaller province
8 in my French is a subset of the first larger province.
9 Thus I cannot tell how many of the anencephalics in the
10 first part are the same as the anencephalics in the
11 second part, thus, doubly counted.

12 There are soldiers who have returned from the
13 South who have children with birth defects. There are
14 also soldiers who never left the North whose children
15 have birth defects.

16 The rate at which those different groups
17 reported to this investigator are different but from the
18 data presented in these papers, I cannot tell how
19 different those rates are since I do not know out of
20 what they have been drawn and with what pressure of
21 selection.

22 The evaluation is I am stuck again with the
23 notion of clinical observation. We have here a set of
24 data with a clinical observation that these things have
25 occurred.

1 Perhaps our focus in further inquiry can be
2 directed a little better. Since I am without a signal
3 anomaly, since I am confronted by the fact that the
4 numbers do not jive with numbers I can generate outside
5 this study and since I believe there are strong forces
6 of differential ascertainment because the rates are low
7 for spontaneous abortion, because the usual anomalies
8 are absent, because the fertility rate in the one study
9 is so high, because the congenital anomaly rate in the
10 second study is so low, I really cannot say anything
11 other than this is a set of clinical observations,
12 intriguing but essentially unvaluable in a standard
13 sort of epidemiologic way.

3A 14 CHAIRMAN SHEPARD: Thank you very much.

15 Dr. Erickson will give us an update on the
16 status of another birth defect study, the outcome of
17 which I think will be very interesting.

18 REPORT ON CENTER FOR DISEASE CONTROL PROPOSED
19 BIRTH DEFECTS STUDY BY DR. J. DAVID ERICKSON

20 DR. ERICKSON: Just to recap what I said
21 at the last meeting of this Committee, CDC has proposed
22 to do a rather large case control study defining cases
23 as babies who are born in the metro Atlanta area over
24 the past decade with birth defects.

25 The controls were normal babies. It is to

1 determine retrospectively whether or not a greater
2 proportion of the fathers of case babies had served in
3 Vietnam in contrast with fathers of normal babies.

4 Around the first of July, Mrs. Harris,
5 Secretary of HHS, gave CDC its marching orders and told
6 us to get busy with the planning for this study. That
7 is what I have been spending virtually all of my time
8 and a good bit of my staff's time doing for the last four
9 weeks.

10 I had two pediatricians assigned to me for
11 the duration of the time it takes to finish with the
12 generation of detailed protocol.

13 We hope to have that protocol completed in
14 about a week and a half. At that time it will be
15 submitted for clearance at CDC; sometime between mid-August
16 and mid-September we will discuss the protocol with the
17 Interagency Committee on Phenoxy Herbicides and
18 Contaminants.

19 In mid-September CDC will assemble a small
20 group of ad hoc consultants to review this protocol which
21 will consist of consultants who will be two epidemiologists,
22 a biostatistician and a medical geneticist familiar with
23 problems of newborn babies.

24 Between mid-September and the end of October,
25 we hope to have the protocol under review by the Office

1 of Management and Budget and hope to have things all
2 squared away to begin hiring personnel at the end of
3 October and collecting data beginning sometime around the
4 first of the year, January of 1981.

5 We plan to be collecting data for one year
6 and hope to have a final report submitted in July of 1982.

7 I would be glad to answer any questions.

8 CHAIRMAN SHEPARD: Thank you. Dr. Suskind?

9 DR. SUSKIND: What would be the size of your
10 population, your birth defect population?

11 DR. ERICKSON: Over the past decade we have
12 on file roughly 12,000 babies who were born with
13 anomalies, roughly half of whom have what we would call
14 a serious anomaly.

15 We are not quite sure yet how many babies
16 will be targeted for study, somewhere on the order of
17 5,000 to 6,000 babies with malformations and something
18 on the order of 3,000 normal babies, it is a very large
19 case control study.

20 DR. SUSKIND: These would be babies born
21 between 1968 and when?

22 DR. ERICKSON: Through 1980.

23 DR. SUSKIND: You are not going to be relating
24 them to Vietnam exposure but you are going to be relating
25 them to phenoxy herbicide exposure?

1 DR. ERICKSON: We are quite hopeful that we
2 can tell whether Vietnam veterans in general are at risk
3 of having babies with birth defects. We are not too
4 optimistic about what we can do about getting down to
5 the question of Agent Orange specifically. We are going
6 to try.

7 Our basic outcome will be whether a man
8 served in Vietnam or he did not.

9 DR. SUSKIND: I think we have the tendency
10 to forget that in these United States, as pointed out
11 by Dr. Kearney in a review some years ago, millions of
12 pounds of 2,4-D and 2,4,5-T were used by gardeners, by
13 home owners, by farmers.

14 The population that grew up through 1970,
15 between 1948 and 1970 had more or less exposure to 2,4,5-T
16 and 2,4-D is still available.

17 It is difficult to identify a non-exposed
18 population. The relative exposure can be determined to
19 some degree by interview.

20 DR. ERICKSON: To some degree.

21 DR. SUSKIND: Not very much.

22 CHAIRMAN SHEPARD: This is going to be the
23 problem with almost any study we do that tries to relate
24 exposure to herbicides in Vietnam and to separate that
25 from other exposures, either here or there.

1 DR. ERICKSON: We will be gathering information
2 about a wide variety of things that are thought to be
3 possible causes or associates of birth defects. We will
4 be able to evaluate those in the population at large
5 and in the Vietnam veterans.

6 It seems to me you must keep in mind the idea
7 that Vietnam veterans may be different from other men
8 in a wide variety of ways other than the possibility
9 of having been exposed to Agent Orange.

10 CHAIRMAN SHEPARD: Thank you, Dr. Erickson.

11 MR. DeYOUNG: In a sense that is all the VA
12 needs to be interested in. I am not speaking now from
13 scientific curiosity but from a benefit structure
14 standpoint.

15 If the statistics show that simple presence
16 in Vietnam differentiates you by a higher increase in
17 birth defects then the rest of the population, that
18 strikes me as probable cause to go ahead and review the
19 benefits.

20 I do not feel personally that we have to be
21 able to say, yes, this is Agent Blue that did this, or
22 Agent Orange, or Agent White, or the crazy karmo over
23 there. It is immaterial to a certain extent.

24 All we have to establish is those veterans
25 do have problems at a greater rate.

1 I personally welcome this study with open arms.

2 CHAIRMAN SHEPARD: Next Dr. Honchar from
3 NIOSH is going to tell us a little bit about the dioxin
4 registry.

5 REPORT ON NIOSH INTERNATIONAL DIOXIN
6 REGISTRY BY DR. PAT HONCHAR

7 DR. HONCHAR: I should start off first by
8 making a distinction between the current effort underway
9 at NIOSH to establish a U.S. registry versus discussions
10 that are currently being held with regard to an
11 international registry.

12 After I complete a brief description of the
13 particular NIOSH effort in the United States, I will
14 relate that to the discussions about an international
15 effort.

16 Right now at NIOSH, I should say for the
17 past year at NIOSH, an exposure registry is
18 being compiled of all people in the United States who
19 have worked at synthesizing 2,4,5-T.

20 The information being collected includes
21 their work histories, how long they worked at this
22 particular type of job and also information about the
23 particular process in use at the industry where they
24 were employed.

25 The ultimate goal of this registry will be

1 for its utilization in a retrospective cohort
2 mortality study. That is, this group of people will be
3 followed historically with questions asked about their
4 cause of death and its comparison to expected rates and
5 expected causes.

6 The registry will include
7 populations from approximately ten different industrial
8 sites within the United States including the sites
9 mentioned by Dr. Suskind earlier.

10 The reason for embarking upon a
11 registry of this type was to increase as much as
12 possible the ability to detect problems within this
13 population. That is, the larger the group of people being
14 reviewed in a mortality study of this type, the more
15 powerful will be the study to detect any rates that
16 are different from expected rates and also to detect
17 types of tumors which may be rare, for example, in the
18 case of carcinogenicity.

19 I should add as a footnote that carcinogeni-
20 city will not be the only cause of death that will be
21 under review by this registry but also non-carcinogenic
22 causes of death; cardiovascular diseases and so on will
23 also be considered.

24 With regard to a status report as I mentioned
25 earlier, the registry has been under formation for

1 approximately a year now. It is still in the data
2 collection phase. We are not to be polite meeting with
3 as much cooperation from all industries as we would like
4 and currently anticipate spending a bit of time enforcing
5 subpoenas for data in the near future.

6 We hope to avoid that but it may be a
7 possibility with some of the industries we are pursuing.
8 There are other industries that we have not yet contacted
9 that will be contacted in the near future.

10 I also said earlier that there are approximately
11 ten industrial sites involved. Each site or I should say
12 many of the sites as far as we have been able to determine
13 were occupied since the 1940's when 2,4,5-T synthesis
14 began by more than one industry, which complicates the
15 issue incredibly. Basically we are looking for
16 historical work histories and personnel records from an
17 industry that may have vacated a site ten to fifteen years
18 ago and was then followed by other companies.

19 The data collection is moving along slowly.

20 My last estimate of the completion time, that
21 is the time until the first analysis could be expected
22 from the entire cohort in the registry is late 1983. Given
23 ongoing problems with regard to finding the data and gaining
24 cooperation from the industries, that date may extend
25 further into the future.

1 I do not present this information as a
2 potential definitive answer to Agent Orange in Vietnam.
3 I certainly would not make a recommendation at this time
4 that if, given other information, that decisions
5 about veterans in Vietnam be held off until 1983 or
6 later.

7 Nonetheless, this study is important because
8 it is an attempt to assemble a large group of people
9 with known exposure to 2,4,5-T through the synthesis
10 process and explore their mortality experience.

11 With regard to the international registry,
12 given that the synthesis of 2,4,5-T is not a labor intensive
13 activity, even workers from the ten U.S. sites may not
14 provide a large enough number to allow the power we would
15 like to see to detect unexpected rates or cause of
16 death.

17
18 Going outside the United States and
19 identifying and including people who have been
20 involved in synthesizing 2,4,5-T from European
21 producers would increase the power of the analysis
22 even further.

23 There are discussions underway. Parties
24 involved to date to my knowledge have been IARC,
25 the International Agency for Research on Cancer; NIEHS

1 and NIOSH. Discussions are on the feasibility of
2 basically replicating the effort as I am conducting
3 it here in the United States outside of the United
4 States, primarily in Europe where most of the
5 non-U.S. producers have existed.

6 All efforts will be made for comparability
7 in data collection if the international registry effort does
8 begin.

9 I think that about covers the major points
10 with regard to the activity. Does anyone have any
11 questions?

12 DR. SUSKIND: When do you anticipate the
13 total registrate population to be within the United States?

14 DR. HONCHAR: I really do not know. That
15 is probably the \$1,000 question. It is very difficult
16 to estimate. We have not yet made our tour of all
17 the industrial sites to collect data.

18 Even if I were to extrapolate right now from
19 expected numbers given the time, to my knowledge, that 2,4,5-T
20 may have been synthesized at a particular site and
21 knowledge on a general level of about how many people
22 may have been involved, the question still remains with
23 regard to whether or not the personnel records are
24 available for inclusion.

25 It is very difficult to estimate. I resist

1 consistently estimating.

2 DR. SUSKIND: What about units that have
3 literally disappeared? Any number of industries that made
4 2,4,5-T in the late 1940's and 1950's are no longer in
5 existence. Their buildings do not even exist.

6 DR. HONCHAR: That is very true. We are
7 finding that in some cases, for example, a parent
8 industry may have held personnel records. We are also
9 exploring for some particular cases situations where
10 hopefully the population could be reassembled or identified
11 through Social Security, by a Social Security I.D. number,
12 or Workmen's Unemployment benefits, things of that sort.

13 The effectiveness of that route of identifying
14 the cohort is directly related to the particular activity
15 at the site.

16 For example, at one site, dealing with the
17 case of mysteriously disappeared records, I know there
18 was no other activity at that site besides the production
19 or synthesis of 2,4,5-T and 2,4-D. If in fact I can
20 identify the cohort and their period of time or work
21 at that site through some other means then direct
22 personnel records of the company, that is a legitimate
23 group for inclusion.

24 There are other means being explored.
25 Obviously the first avenue is the particular companies.

1 CHAIRMAN SHEPARD: Are there further
2 questions?

3 DR. GROSS: On the reluctance to provide
4 records and the subpoenas, do you suppose if certain
5 waivers telling the people that the displeasure of
6 Uncle Sam may be visited to them if they do not cooperate
7 would help? The statute of limitations must have
8 expired.

9 Do you not believe that a great deal of
10 records could be obtained from industry if such
11 assurances were given that there would be no prosecution
12 or regulatory action against them?

13 MAJOR BROWN: I think one of the problems you
14 might have in that case is it does not limit the company
15 from third party liabilities.

16 DR. GROSS: Civil type actions.

17 MR. DeYOUNG: The question of when that statute
18 of limitations begins to run much less when it runs out.

19 CHAIRMAN SHEPARD: We are running a little
20 behind schedule. I want to continue. I do want to have
21 some time for questions. We will stay here for a
22 reasonable period of time hopefully to answer those
23 questions.

24 I would now like to call on Dr. Carolyn
25 Lingeman from National Cancer Institute on

1 loan to AFIP, who will bring us up to date on the status
2 of the AFIP registry and discuss a couple of proposals
3 she has made.

4 REPORT ON AFIP REGISTRY AND PROPOSED
5 STUDIES BY DR. CAROLYN LINGEMAN

6 DR. LINGEMAN: As you know, there is a registry
7 of environmental pathology at the AFIP. This is the
8 registry headed up by Dr. Nelson Irey who is doing
9 pathologic documentation for the VA's registry on Agent
10 Orange.

11 So far there have been 58 accessions there of
12 which 14 are neoplasms. These do not fall into any kind
13 of pattern. This is essentially a pathologic back-up
14 for a cohort study. Eventually there might be
15 possibilities of some type of epidemiologic analysis of
16 this kind of material.

17 We certainly do need the pathologic
18 documentation and perhaps the important thing is if there
19 are 26,000 people now in the VA Agent
20 Orange registry, maybe a bigger effort could be made to
21 find out how many of those are neoplasms and get the
22 pathologic material in for evaluation.

23 CHAIRMAN SHEPARD: Excuse me. Let me clarify
24 a misconception that may be there. The 26,000 that I
25 referred to are Vietnam veterans who have entered the

1 registry. We do not have anything like that number who
2 have submitted any tissue. There probably would be a
3 very small handful of those.

4 DR. LINGEMAN: If a diagnosis of neoplasia has
5 been made, this would imply that a biopsy was done.

6 The other type of epidemiologic study which
7 might be possible using AFIP material would be case
8 control studies. I think there we have an opportunity
9 which probably does not exist in very many centers, of
10 having access to relatively large numbers of rare or
11 infrequent neoplasms.

12 The AFIP has a registry of soft tissue tumors.

13 We have already had preliminary conversations
14 with the Chairman of the Soft Tissue Pathology Department
15 about a proposed study but do not know if it can be done.

16 As we develop plans for a study designed to con-
17 firm or disprove the Swedish studies, perhaps we will ask
18 Dr. Suskind and others on this Committee to review the
19 protocol.

20 Such a study may provide only negative
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1 answers but as scientists, we are only obliged to provide
2 scientific answers. These will not be social answers or
3 legal answers. It is important that this Committee concern
4 itself only with scientific issues, not legal ones.

5 One thing I do notice in the Swedish studies is
6 that nine of the soft tissue tumors were angiosarcomas which
7 as you know are extremely rare neoplasms in the United
8 States. Only about 50 occur each year in the United States.

9 We have had a cluster of angiosarcomas in an
10 industry that manufactured chlorinated compounds of a different
11 type. As you recall, vinyl chloride has been associated
12 with angiosarcomas of the liver. In the case of vinyl
13 chloride, the angiosarcomas is what might be called a
14 signal neoplasm.

15 In the Eriksson study there may have been an excess
16 of angiosarcomas. As in the Swedish studies, we would
17 attempt to determine whether or not people with soft tissue
18 neoplasms might have been exposed to phenoxy herbicides.

19 But I wish to emphasize that these studies are
20 only in the very early talking stages.

21 The other problem of concern to us is the
22
23
24
25

1 controls. We are currently working on another case control
2 study involving neoplasms of the sinonasal tract, and are
3 using cases from AFIP data base for controls. These are
4 all sick people. Which ones do we exclude and how do we
5 decide which ones to exclude? We can match the controls
6 by age, sex, race and even geographic location by state.

7 We welcome comments from the epidemiologists as
8 to what kind of groups we can use for controls.

9 CHAIRMAN SHEPARD: Thank you very much,
10 Dr. Lingeman.

11 You did mention the testicular tumor?

12 DR. LINGEMAN: That was the other group we talked
13 about. It turns out two of the three we have in the Registry
14 so far are from the same patient. We actually only had two
15 patients with testicular tumors. Both were young men. Testi-
16 cular neoplasms are among the most frequent neoplasms in
17 young men.

18 Others have mentioned testicular neoplasms as one
19 type that may be showing up in the Vietnam veterans. Probably
20 this is the second most important type of neoplasm for a case-
21 control study. We will see what we can do.

22 CHAIRMAN SHEPARD: I think this is a very
23 important announcement because the AFIP does have a vast
24 store of material, and I guess all of it is computerized.

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1 It has been put in there very carefully and
2 can be analyzed relatively easily.

3 We are looking forward to the results of those
4 studies. Thank you.

5 We would like to hear from Major Phillip
6 Brown of the Air Force on the status of the Ranch Hand
7 Study which as all of you know has gotten a lot of
8 visibility. Due to the fact this is a cohort with
9 relatively precise exposure data and probably the only
10 such cohort that exists, we are looking with great
11 interest to the development of this study.

12 Major Brown?

13 REPORT ON THE RANCH HAND STUDY BY
14 MAJOR PHILLIP G. BROWN

15 MAJOR BROWN: Thank you, sir.

16 I think it would be worthwhile to review a
17 little bit of the past history, hopefully most of you
18 know of it but maybe not all.

19 The Air Force as early as 1978 was
20 volunteered to
21 begin to examine the possibility of an epidemiology
22 study regarding the Ranch Hand personnel that flew the
23 missions in Vietnam.

24 It has taken us many months to get to the
25 point now, as of 1 August to have a recommendation by the

1 Interagency Work Group to the White House recommending
2 that the Air Force do the study.

3 At this time it is my understanding that this
4 recommendation is under consideration by the White House.
5 Until such time as we get guidance, the Air Force will
6 still be in the situation of waiting but still doing some
7 work.

8 We have identified the population in terms of
9 the exposed individuals. We are now certain there are
10 1,160 personnel that flew the herbicide in Vietnam over
11 the years. We had originally said an estimate of 1,200.
12 We came out fairly close.

13 We have started the process and are well along
14 the way of identifying the controls for those individuals.
15 We believe there is going to be an extremely tight match
16 because we have a very large population for the controls.

17 We are in the process of locating the
18 individuals that flew, thanks to the legislation that
19 occurred in Congress recently. We were able to contact
20 the I.R.S. and by that legislation they have been obliged
21 to tell us the last whereabouts of these individuals
22 via their income tax returns.

23 It has been extremely helpful. It is one
24 of those rare events that occurs every once in a while.

25

1 We are doing an extremely large amount of work.
2 We are refining the protocol. The Scientific Panel of
3 the Interagency Group recommended a twenty year follow-up.
4 That may have great precedence within the Federal sector
5 for a study, since I am not aware of any that has been
6 programmed for that long.

7 This has obviously taken some thinking in
8 terms of the Air Force about programming and the size
9 of contributions that might be required to do the study.

10 CHAIRMAN SHEPARD: Thank you. Are there any
11 questions for Major Brown?

12 MR. DeYOUNG: You say you have a large control
13 population from which to draw. What kind of group is
14 that? Air Force personnel who have not been to Vietnam?

15 MAJOR BROWN: These are Air Force personnel
16 who were in the Vietnam theater of operation.

17 MR. DeYOUNG: Not involved in the Ranch Hand?

18 MAJOR BROWN: That is correct, not exposed.

19 MR. DeYOUNG: I believe there was some talk
20 at our last meeting about having this Committee review
21 that protocol. Is that an offer from the Air Force
22 or a request from the Committee or am I totally
23 misremembering it?

24 CHAIRMAN SHEPARD: I do not recall. There are
25 some members of this Committee who also serve as members

1 of the Scientific Panel of the Interagency Work Group. I
2 do not recall any specific offer or commitment on the
3 part of this Committee to do that.

4 DR. SUSKIND: Has the logistics of carrying
5 out the study been explored?

6 MAJOR BROWN: As you are well aware,
7 Dr. Suskind, because of your studies, that is a major
8 problem. We are aware some of these individuals no longer
9 reside in the United States. We will have a logistics
10 problem. We have been exploring that to see what is the
11 best methodology for it.

12 There are a number of options and no particular
13 option has yet been identified.

14 CHAIRMAN SHEPARD: Thank you very much,
15 Major Brown. We will follow the progress of this with
16 great interest.

17 Dr. Kearney would like to tell us a little bit
18 about the activities of the Department of Agriculture
19 and their involvement with the whole issue of herbicides.

20 REPORT ON DEPARTMENT OF AGRICULTURE
21 ACTIVITIES BY DR. PHILIP KEARNEY

22 DR. KEARNEY: Mr. Chairman, it is running late
23 and I did prepare some written comments. In the interest
24 of time, I will just pass these out to the Committee.

25 It describes the title of the contact person,

1 the date of completion. I see nothing wrong with anyone
2 contacting these people to learn the status. I do not
3 know that they need discussion.

4 CHAIRMAN SHEPARD: Thank you very much. I
5 appreciate your sensitivity to the lateness of the hour.
6 I really appreciate your putting this together.

7 As many of you know, the use of herbicides
8 obviously impacts heavily on the forestry and
9 agricultural industries of this country. Those agencies
10 and activities involved in that work are following this
11 whole issue very closely and are conducting studies
12 parallel to some you have heard about.

13 I apologize for the fact that we have run over
14 by about half an hour. I do want to take some time to
15 recognize some of the questions to come forward.

16 Let's take a short break and return for
17 questions and answers.

18 (Whereupon, a short recess was held from
19 12:03 p.m. to 12:10 p.m.)

20 CHAIRMAN SHEPARD: Let's reconvene, ladies
21 and gentlemen.

22 We have a number of written questions. We
23 will attempt to answer as many of them as possible.

24 I feel a little uncomfortable about asking
25 the members of the Committee to stay beyond 12:30 p.m. or

1 12:40 p.m. I will be happy to stay for as long as
2 necessary and do my best to answer questions that have
3 come in.

4 In the event that we do not get your questions
5 answered, we will answer you in writing if we have your
6 names and addresses.

7 I have a group of four typewritten questions
8 with the name of Frank Latonzee from Citizen Soldier. We
9 will start off with one of Mr. Latonzee's questions.

10 I will read the four and maybe you can
11 identify the most important one you would like answered
12 first and then we will continue with the others.

13 Why has not the VA developed a standardized
14 clinical protocol for examining Vietnam veterans by all
15 VA facilities?

16 I can answer that there is a reasonably
17 standardized protocol in the form of our instructions to
18 VA facilities. There is something of a protocol that is
19 in the form of instructions to the VA facilities as to
20 how these examinations are to be conducted.

21 Obviously if you are dealing with a large
22 population, both of veterans and physicians, with a wide
23 variety of ailments, conditions or complaints, it is
24 very difficult to standardize a protocol. There will
25 be an individual variation on the part of the physician

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1 as the needs require.

2 Why is no data taken from veterans' wives?

3 Why has not the VA implemented standardized
4 precoded questionnaire forms for all VA facilities? That
5 has been done.

6 We do have a standardized questionnaire.
7 Maybe you have a more specific question relating to that.

8 What protocol has the VA established to help
9 incarcerated veterans obtain Agent Orange examinations?

10 I can very quickly answer that. The VA is
11 not authorized to enter penal facilities. We will make
12 available to any medical departments of those facilities
13 our questionnaire and the instructions so in the event
14 the medical departments of those penal facilities are
15 capable of carrying out the same instructions that we
16 provide to our own physicians.

17 We would be happy to receive the data which
18 comes forth from that.

19 Why has not the VA actively pursued the
20 development of bioassay methods other than fat tissue
21 analysis including the new RNA blood analysis techniques
22 which were developed in-house by VA doctors in the Bronx
23 VA?

24 I do not have the information to answer that.
25 Dr. Hobson?

1 DR. HOBSON: I think they are referring to the
2 RIA. There has been some work done in an attempt to
3 identify TCDD in blood. At the present time that has
4 not proved sensitive enough nor has it been validated to
5 the point where it has any usefulness in correlation
6 with exposure in the past.

7 The other thing in that regard is while you
8 can detect dioxin by various methods, immediately after
9 exposure to the blood, material does not hang around in
10 the blood for a long period of time. It is disposed of
11 by the body either by discretion or by depositing it in
12 fat and other tissues.

13 The likelihood of finding circulating
14 dioxin ten years or so after exposure is a priori,
15 pretty slim.

16 CHAIRMAN SHEPARD: Thank you.

17 We have a group of questions from the Veterans
18 of Vietnam War, Post #1. Is this from Pennsylvania?

19 MR. BISSLAND: Scranton, Pennsylvania.

20 CHAIRMAN SHEPARD: We welcome your
21 participation and are pleased you saw fit to take the
22 trip.

23 Some of these are in the form of questions
24 and some are in the form of comments.

25 Is the VA Hospital going to continue with

1 present tests or will they be upgraded?

2 I am not sure if you are referring to a
3 specific VA hospital. I will answer the question
4 assuming you mean the VA hospital system.

5 We are in the process as I think I indicated
6 earlier and if I did not, I meant to, that we have
7 observed some problems with the use of our questionnaire.
8 We think there are some questions there that most
9 veterans find difficult to answer and probably there are
10 questions that perhaps are not there and should be there.

11 A subcommittee of Dr. Page's group is working
12 hard to revise the questionnaire and improve the
13 questionnaire. As soon as that has been approved by
14 the Agency and has been tested and has been found to be
15 an improvement on the existing system, we will circulate
16 it for implementation.

17 What methods and to what extent will be used
18 to determine dioxin present in veterans?

19 I think Dr. Hobson has alluded to that.
20 Maybe I could amplify it a little. The whole technique
21 of measuring dioxin in the body is a very, very difficult
22 one. We are talking about parts per trillion of dioxin
23 in body fat, that is, the limited work that has been
24 done in that area already.

25 The fat biopsy effort that has been undertaken

1 was a test of the analytical technology that exists in
2 the country. There are relatively few laboratories that
3 are capable of doing this very sensitive test.

4 I think the studies that have been done or
5 the attempts to measure dioxin in the body first of all
6 are exquisitely difficult and furthermore, we do not have
7 a strong impression that there is a high level of
8 correlation between measurable detectable levels and
9 exposure to Agent Orange.

10 I think that brings into question the
11 usefulness of this very difficult and expensive test.

12 If other members of the Panel have anything
13 to add to my answers, please feel free to jump in.

14 What percent of disability will be awarded and
15 when?

16 (LAUGHTER.)

17 CHAIRMAN SHEPARD: I think I understand where
18 this question is coming from. The whole problem of
19 disability compensation continues to be of concern.

20 As I think I mentioned earlier, we are
21 working hard to make the point that the disability does
22 not have to be related to any demonstrated exposure to
23 Agent Orange or any other substance. The association
24 of a disability with military service is the only
25 requirement. To date, that process continues.

1 We are looking in all our studies for evidence
2 of linkage of Agent Orange or service in Vietnam to
3 disabilities. Certainly the data that comes from our
4 registry should give us a clue as to what disabilities do
5 exist in the Vietnam veteran population.

T-3B 6 MR. BISSLAND: When a veteran does go to a
7 VA hospital for an examination, what is done with that
8 data that is taken by the doctor?

9 If there is an ailment, they have a
10 tendency not to notify the veteran of the ailment and
11 as a case in point we had a member who had an Agent
12 Orange examination and the liver case came back and
13 proved there was something wrong with his liver.

14 He went back for another test and it was not
15 as bad as it was before. A week later, he was cured.
16 Remarkable!

17 CHAIRMAN SHEPARD: That is not unusual. It
18 is quite common in liver ailments. For example,
19 hepatitis and jaundice is a group of diseases which
20 affect the liver. One of the ways of detecting that
21 other than the yellow appearance of the eyeballs or the
22 skin is through a battery of liver enzyme tests.

23 Characteristically, this is a self limiting
24 disease and the enzymes return to normal in a varying
25 amount of time.

1 It is not unusual for somebody to have
2 hepatitis and to recover spontaneously. In
3 fact, correct me if I am wrong, there is no known cure
4 or medicine for that particular illness.

5 What you described is not an unusual thing.
6 You asked a question about follow-up.

7 MR. BISSLAND: We have patients who do not
8 know what is happening. They go for tests and hear
9 nothing more.

10 CHAIRMAN SHEPARD: That I have heard and it
11 is regrettable. I hope when that is the case it means
12 the studies have come back normal.

13 We are pursuing efforts to improve the
14 follow-up procedure. I feel very strongly that regardless
15 of what the results of your examination are, that each
16 veteran should be informed and we have that obligation,
17 and invite him to question the results in any way he
18 sees fit.

" We are attempting to improve our follow-up
" process.

21 Since present studies will not be completed
22 for some time, what about vets who are suffering now and
23 if vets die in the meantime, will their families be
24 taken care of or will their death certificate read
25 "cause unknown"?

1 There are a lot of questions in that comment.
2 Let me take the first part. Since present studies will
3 not be completed for some time, what about vets who
4 are suffering now?

5 Any veteran, be he a Vietnam veteran or
6 any other veteran who is eligible for care in a VA
7 hospital obviously can have his problems taken care of
8 now. The question of eligibility is a fairly complex
9 one and I do not think I will take the time now to
10 describe it in detail. Part of that is the fact that
11 I do not know all of it in detail.

12 If there are illnesses demonstrated at the
13 present time, there are mechanisms for having that
14 illness treated in VA facilities.

15 About the Vietnam veteran who dies, will his
16 family be taken care of; that is a little out of my
17 area of expertise. It is my understanding that death
18 benefits and survivor benefits are available under
19 certain circumstances.

20 DR. HOBSON: If I could make a comment, these
21 questions that go to compensation and pension are coming
22 to the wrong people. I think there is no one in the
23 room right now who is in compensation and pension.

24 I think frankly it is going to be misleading
25 if we attempt to answer them here. We may give you

1 misinformation. Since this was a scientific panel, they
2 were not asked to be represented on it. I think these
3 questions are probably a little out of line although they
4 certainly are germane and ones that demand answers.

5 This is just not the proper place to get the
6 answers.

7 CHAIRMAN SHEPARD: Thank you.

8 Many veterans are regular blood donors. Many
9 of these veterans are finding they have dioxin in their
10 blood. I would question that.

11 MR. ROXBY: I work with people who have the
12 medical reports back that say they have a percentage of
13 dioxin in their blood.

14 DR. HOBSON: Which hospitals?

15 MR. ROXBY: The Wilkes-Barre Hospital.

16 CHAIRMAN SHEPARD: We will look into that. I
17 am not aware of any VA facility that is measuring dioxin
18 levels.

19 MR. ROXBY: If the tests are accurate and
20 true and this man does have dioxin in his blood, does
21 this or does this not put some type of contamination
22 in to the recipient of that blood?

23 CHAIRMAN SHEPARD: Obviously if someone had
24 dioxin in their blood, it would represent a contaminant.
25 I really question the ability to my knowledge of any VA

1 hospital measuring dioxin levels in blood.

2 MR. ROXBY: You are questioning the VA hospital
3 in Wilkes-Barre.

4 CHAIRMAN SHEPARD: I am questioning the source
5 of that information.

6 MR. ROXBY: That can be documented. It did
7 come from a VA hospital.

8 CHAIRMAN SHEPARD: We will certainly look into
9 it.

10 Those are all the questions I have. There is
11 one request from Mr. Roxby to address the Committee. I
12 would entertain such an address for a few minutes.

13 MR. ROXBY: If I wanted to say everything I
14 have to say, you would be here another three days about
15 what has been going on with me since 1974.

16 All I have been hearing about is chloracne.
17 It is the only thing being related to exposure to Agent
18 Orange, TCDD.

19 The Comptroller General had a study made with
20 other findings possibly with the soils. If I take my
21 shirt off, I can show you. I know how much pain there
22 is having this stuff on your body. The weakness is
23 unreal. I cannot get out of a chair without help
24 sometimes. Weight loss, almost 50 pounds in four years.
25 Nausea, I cannot eat or drink without losing half of it

1 five minutes later. Urinary tract, I have no control
2 half the time. If I have to go, I have to make sure I
3 am there or I will go where I am at.

4 My sex life is completely shot. I am 34 years
5 old. I do not know what it is to go to bed with a woman
6 and that has been for four years now.

7 Mobility and drive; I cannot move my arms
8 and legs. Anger and frustration, no one would like to
9 get up and argue with me, I would blow them away.

10 Stiffening of the hands, arms, legs, the
11 neck muscles, headaches, breathing difficulty, swallowing,
12 I am almost on baby food. I have had diarrhea for four
13 years.

14 All this, every one of them has been documented
15 in the article published by the Comptroller General.
16 There are follow-ups on it. I had a copy sent up from
17 the VA hospital in Lancaster.

18 I am just wondering why all these symptoms can
19 be in a book and I have them and I will go back in the
20 hospital like I have been for the last six years, why
21 the only issue coming up is chloracne. Chloracne seems
22 to be the littlest problem of them all listed.

23 It is the smallest but it is the only one
24 being thrown in our face. For all this, I get \$5.00
25 a month disability. I get \$165 after that because I am

1 house bound and need regular aid. That is my disability.

2 CHAIRMAN SHEPARD: Are you getting care in your
3 VA hospital?

4 MR. ROXBY: Anything I want. I get my care
5 at the Wilkes-Barre Hospital and I have been treated at
6 both the Philadelphia VA and the Wilkes-Barre. I have
7 been treated for everything from frostbite to burgers
8 disease from Vietnam.

9 CHAIRMAN SHEPARD: Have you filed a claim?

10 MR. ROXBY: They do not seem to have records
11 of my having an Agent Orange test. I have to go through it
12 again. The papers for my claim are going in again for
13 the second time.

14 CHAIRMAN SHEPARD: I certainly sympathize with
15 your problem. I hope you are getting good care at
16 the Wilkes-Barre Hospital. I want to encourage you not
17 to try to conclude that your problem which is a very
18 serious problem and just looking at you I would suspect
19 it is scleredema in some form, the symptom complex you
20 described is fairly classic for that condition.

21 MR. ROXBY: I have been doing a good deal
22 of reading on what I have been treated for. The symptoms
23 I have will point to scleredema but they also point to
24 dioxin poisoning. You have them back to back.

25 They were rather tell me I have scleredema,

1 non-service-connected instead of turning around and
2 saying I have dioxin poisoning. That is what it comes
3 down to.

4 CHAIRMAN SHEPARD: You are approaching the
5 problem from the point of view of filing a claim. I do
6 not have the expertise and we do not have all the
7 records here to examine but I think you should pursue
8 the possibility that this may have been a service
9 connected problem.

10 The issue of relationship to dioxin is
11 probably not your strongest case. A much stronger case
12 is the fact that you had some of the early signs of this
13 condition while you were in service or shortly after
14 service.

15 MR. ROXBY: I had the rash right down my entire
16 left side going across my chest. It does not seem to
17 relate. I have been getting nowhere as far as the
18 Veterans Administration is concerned.

19 Every time I fill out a form to send it in,
20 I have to start looking through papers and so forth
21 describing when it started. After I send that form out,
22 I get another and they want the same information.

23 CHAIRMAN SHEPARD: Let me say we will look
24 into it. We will be in touch with the hospital in
25 Wilkes-Barre.

1 MR. ROXBY: I have also been denied copies
2 of my medical records and tests which I believe is
3 illegal under the Freedom of Information Act.

4 CHAIRMAN SHEPARD: We will be happy to look
5 into that and get back to you.

6 DR. HOBSON: Request under the Privacy Act
7 and not under the Freedom of Information Act.

8 MR. DeYOUNG: We have had that happen to
9 people in the Midwest as well and our response is to
10 simply march into the Director of Information Office
11 for that particular hospital and ask politely in an
12 assertive manner, insist on your rights under the
13 Privacy Act. You are entitled to a hand carried copy
14 of any tests as of that date.

15 MR. ROXBY: At the Wilkes-Barre Hospital you
16 will be marched out the door. I sent away for my
17 records in Missouri under the standard Government form
18 stating what records I wanted. I was denied those
19 records. I was sent back my discharge papers and that
20 was it, my 242.

21 MR. DeYOUNG: Did they specifically say
22 you could not have those records?

23 MR. ROXBY: They specifically did not send
24 those to me.

25 MR. DeYOUNG: They did not understand you.

1 MR. ROXBY: Conveniently misunderstood me.
2 If I wanted a copy of my DDT-14 form, I would have asked
3 for it.

4 MR. DeYOUNG: The grapevine tells me that
5 the records at Missouri that you are asking for, all
6 those requests are simply piling up on some fellow's
7 desk, some GS-9 down there who sits there scratching
8 his head and saying, what do I do with these? No one
9 has worked out the system for coping with those
10 responses yet.

11 I am not trying to make excuses for the
12 Government. That is not my job.

13 The bottom line to the vet is do not hold your
14 breath for those records because you are not going to get
15 them.

16 CHAIRMAN SHEPARD: That concludes the written
17 questions. Dr. Rogan?

18 DR. ROGAN: I would like to add in reference
19 to my discussion earlier that the crude birth rate in
20 the North Vietnamese study was 75 per 1,000 population
21 year. The 400 was a per woman year number adjusted for
22 a spontaneous abortion rate of 15 percent. Thus, 400
23 pregnancies per 100 woman years.

24 CHAIRMAN SHEPARD: Thank you.

25 I would have the Committee stand adjourned

1 and would like to express my great appreciation for the
2 participation of all members of the Panel, the
3 forbearance of the audience and their interest in this
4 issue.

5 I again want to express my appreciation for
6 all the hard work that has been done to coordinate this
7 meeting and look forward to seeing you again.

8 Thank you.

9 (Whereupon, the meeting was adjourned at
10 12:35 p.m.)

C E R T I F I C A T E

This is to certify that the foregoing proceedings before the Veterans Administration, Advisory Committee on Health Related Effects of Herbicides, Wednesday, August 6, 1980, were had as herein appears and that this is the original transcript thereof.

Marilynn M. Nations
MARILYNN M. NATIONS

I hereby certify that the proceedings and evidence herein are contained fully and accurately, as corrected.

Barclay M. Shepard
BARCLAY M. SHEPARD, M.D.
Chairman
VA Advisory Committee on Health-
Related Effects of Herbicides

November 3, 1980

Advisory Committee on Health-Related Effects of Herbicides Transcript of Proceedings

**(Sixth Meeting
November 6, 1980)**

VETERANS ADMINISTRATION**ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS OF HERBICIDES**

- - -

Thursday, November 6, 1980
Veterans Administration Central Office
Room 119
810 Vermont Avenue, N.W.
Washington, D.C.

The Committee met, pursuant to notice, at 8:35
a.m., Barclay M. Shepard, M.D., Chairman, presiding.

ATTENDEES:

Barclay M. Shepard, M.D., Chairman,
Veterans Administration

Ronald W. DeYoung, National Veterans
Task Force on Agent Orange

J. David Erickson, D.D.S.
Center for Disease Control

Thomas J. FitzGerald, M.D., American
Legion, for Irving B. Brick, M.D.

Adrian Gross, M.D.
Environmental Protection Agency

Lt.Col. Richard A. Hodder
Uniformed Services University of
The Health Services

Ralph Ross, Ph.D., Department of
Agriculture, for Philip C. Kearney, Ph.D.

Carolyn H. Lingeman, M.D.
National Cancer Institute

Sheldon D. Murphy, Ph.D.
University of Texas Medical School

Charles A. Thompson, Disabled American Veterans
For Robert H. Lenham

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P R O C E E D I N G S

Dr. SHEPARD: Good morning. Welcome to our quarterly meeting of the VA Advisory Committee on Health-Related Effects of Herbicides. We are pleased that you are all here, both as observers and as members of our Committee, and we hope this will be another productive session.

I have a few announcements to make.

We are very pleased to have a new member of the Advisory Committee in the person of Lieutenant Colonel Richard A. Hodder. I hope he'll arrive shortly. He has been invited to be a member to replace Colonel Thiessen who has resigned from our Committee due to his retirement from the Army.

Colonel Hodder is currently Director of Epidemiology in the Department of Preventive Medicine and Biometrics at the Uniformed Services University of the Health Sciences, a new medical school on the Bethesda Naval Hospital Campus.

Dr. Hodder is a medical epidemiologist, and we are very pleased that he will be a member of our Committee, and we look forward to working with him.

I have a letter from Dr. Abraham Lilienfeld which I would like to read to you. This was addressed to Dr. Haber, since Dr. Haber was my predecessor in this job:

1 "You may have wondered about my absence at the
2 Herbicide Advisory Committee meetings during the past several
3 months. What happened was that in April I was made Director
4 of the MPH Program at our School, at the request of the Dean.
5 This includes an effort to review the program, evaluate it,
6 and make curriculum changes necessary, etc. This has, as you
7 might expect, taken an inordinate amount of time in the last
8 4-5 months.

9 "In view of these additional responsibilities, I
10 regret to say that it will be difficult for me to continue
11 to serve in an advisory capacity. I'd rather admit this than
12 find myself in the position of not being able to attend meet-
13 ings on designated days or to respond to a variety of requests.

14 "I feel certain that you understand my position in
15 this matter.

16 "Best personal regards, Sincerely, Abraham
17 Lilienfeld."

18 We regret Dr. Lilienfeld's resignation, but certainly
19 understand with the press of duties in his new responsibilities,
20 his inability to continue as a member of this Committee, and
21 we are now making efforts to secure a replacement for him.

22 We are very pleased to have with us this morning
23 Dr. William Gaffey, Manager of Epidemiology in the Department
24 of Medicine and Environmental Health for the Monsanto Company
25 in St. Louis. Dr. Gaffey co-authored a recent study analyzing

1 the relationship between TCDD and the cause of death of 58
2 employees potentially exposed to the contaminant during
3 2,4,5-T herbicide production at the company's Nitro,
4 West Virginia, plant.

5 Dr. Gaffey has very kindly consented to appear on
6 the program today and bring us up-to-date on some of the
7 recent studies that he has been conducting.

8 As in previous meetings, we will have a time for
9 questions at the close of our formal presentations. I would
10 encourage all of you who have questions to please write them
11 out and send them forward so they may be included in our
12 discussion period. There are cards, pencils, and so forth
13 in the rear of the room. If you have a question, please so
14 indicate and our secretary will be happy to provide you
15 with the materials.

16 We have received a notice of some correspondence
17 relating to a reference that was made at a previous meeting --
18 not a recent meeting. It was before I became Chairman. I
19 think Mr. Ron DeYoung had made a comment at the December 12
20 meeting concerning the possible destruction of records as a
21 result of a fire in the Regional Office in Chicago.

22 We have looked into this matter and I will include
23 the report of that fire in the minutes for the sake of com-
24 pleteness. I will just read to you a portion of that
25 report so you will understand what the bottom line is.

1 This was a fire that occurred on January 31, 1979. The fire
2 caused extensive damage within the Adjudication Division
3 of the Chicago Regional Office.

4 "The Adjudication Officer's office was destroyed
5 and other areas adjacent to that room were extensively damaged
6 by fire and water.

7 "There were no veterans' records in the Adjudication
8 Officer's office at that time. Some veterans' records in
9 the Assistant Adjudication Officer's office were scorched
10 from the intense heat, as were some in the filing cabinets
11 nearest the fire, but there was no irreparable damage.

12 "Several efforts were made to obtain an explanation
13 of Mr. DeYoung's allegation of the loss of Agent Orange 526
14 claim forms. All 526 forms were accounted for in the individ-
15 ual veteran's claims folders. It was learned that a handwritten
16 listing in the Adjudication Officer's desk contained the names
17 and file numbers of veterans who had filed claims identifying
18 Agent Orange as the disability which had been received by
19 that office. This personal reference list was destroyed but
20 was re-constructed based on records maintained elsewhere in
21 the Division."

22 So just for those of you who might have had
23 some lingering doubts about claims that had been destroyed
24 that apparently did not occur and there was no loss of that
25 process as a result of the fire.

1
2 MR. DeYOUNG: Excuse me. I double-checked that.
3 My concern in asking the question is answered. The way
4 it was brought to me by the veterans who were concerned
5 about it was that a locator list of some sort which
6 maintained the contact or could potentially maintain re-
7 contact with these 500 and some odd veterans was destroyed.

8 Now, it's my understanding that this has been
9 recompiled, so that that fire at the Chicago RO will not
10 cause any problem, as I understand.

11 DR. SHEPARD: Thank you.

12 To those of you who have not signed in, please
13 do so in the book at the rear of the room. We are very
14 anxious to maintain a list of attendees.

15
16 Also, we would like to establish and maintain a
17 mailing list of interested individuals. Please in-
18 clude your address so that we may send you materials
19 from time to time-- notices of meetings, and that sort of
20 thing. We would appreciate your doing that.

21 Just a few other brief comments. As indicative
22 of the continuing high level of interest in the Agent
23 Orange program and issue, there has been considerable
24 interest on the part of congressional committees. And as
25 many of you, I'm sure, know, we have had during the past

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1 few months three hearings -- on September 10th, the hear-
2 ing before the Senate Committee on Veterans Affairs; on
3 the 16th of September, a hearing before the House Com-
4 mittee on Veterans Affairs; on the 25th of September,
5 the House Committee on Interstate and Foreign Commerce,
6 Subcommittee on Oversight and Investigation.

7 That latter one is the first time that the VA
8 had been asked to testify before that committee.

9 For any of you who are interested, we have
10 copies of the prepared statements that were used, and we
11 would be happy to supply those to you. I think, as a mat-
12 ter of fact, in the package to the members, there
13 is a copy of one of those hearings statements.

14 Some of you are aware of the fact that I was
15 privileged recently to attend, in Rome, an international
16 workshop on dioxins. This was held the 22nd through
17 24th of October. I'll just make a very brief report on
18 that meeting.

19 The meeting was sponsored by a number of groups,
20 two international societies: One, the International
21 Society of Environmental and Analytical Chemistry, and
22 the International Society of Toxicological Environmental
23 Chemists.

24 In addition, the Istituto Superiore di Sanità,
25 which, I guess, would correspond to the National Institutes

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1 of Health in this country, a regional office set up in
2 Seveso by the Lombardy region, the National Research
3 Council of Italy, and the Hoffman-LaRoche Company of
4 Switzerland were involved.

5 It was a very full three-day meeting. Sessions
6 went from nine o'clock in the morning until seven-thirty
7 in the evening, and was very well attended. I would guess
8 there were 100 to 150 scientists and participants.
9 A total of 56 papers were presented in six general
10 areas.

11 First, a section on analytical methodology, in
12 which many papers were presented on such interesting
13 topics as isomer differentiation of the 22 isomers of
14 TCDD. We've been talking a lot about the difficulty of
15 separating these 22 isomers, not all of which are toxic,
16 but some of which are very toxic. And it was interesting
17 to learn that the technology does exist for the separa-
18 tion of these isomers.

19 Another section on environmental fate and
20 levels discussed the effect of the environment on these
21 chemicals.

22 There was one very interesting section enti-
23 tled The Incineration Story. There's a very high level of
24 concern in many parts of the world on the effects on the
25 environment of municipal and chemical incineration, solid

1 waste disposals and chemical disposals. And many inter-
2 esting theories were propounded as to how some of these
3 chemicals are formed and released into the atmosphere.
4 So there was a very interesting section on that.

5 There was a section on biochemical toxicology
6 and metabolism; another section on animal toxicology;
7 and one section on observations in men.

8 There will be a transcript of the proceedings of
9 this meeting, which I hope will be out in another couple
10 of months. I will receive a copy as an attendee, and I
11 think it will be interesting to make distribution of that
12 information and incorporate it in our body of information.

13 It was very interesting to me to see how many
14 individual company scientists are really concerned about
15 the TCDD and related compounds. It was really an eye
16 opener to see the high level of interest and the efforts
17 that are going into solving some of these problems.

18 We think in this context of herbicides as being
19 the main issue, and, of course, for the Agent Orange prob-
20 lem it is. But there are many other sources of dioxins.
21 In fact, the ubiquitous nature of dioxins is something I
22 had not fully appreciated. And this was brought out in
23 these discussions.

24 Well, so much for that. I recommend Rome to
25 you. It's a beautiful city. The weather was lovely and

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1 we really enjoyed being there.

2 Any questions on that? As I say, we will have
3 the proceedings of the meeting.

4 DR. MURPHY: Dr. Shepard.

5 DR. SHEPARD: Yes, sir.

6 DR. MURPHY: I recently saw a three-line
7 newspaper statement about a suspicion that 200 or 800
8 sheep had been grazing in the Seveso area and had become
9 ill. Was that discussed at that meeting?

10 DR. SHEPARD: No, it wasn't discussed. It
11 happened while the meeting was going on. This was on
12 Thursday the 23rd of October, right in the middle of the
13 meeting. I didn't hear about it until I got back.
14 Apparently it appeared in the press, and I was asked to
15 look into it and report on it to the Administrator.

16 As a result of my having been in Rome, I knew
17 who to call, and I did call and found out. Yes, there
18 were 200 sheep that had been grazing in the vicinity of
19 Seveso, or that 200 of the sheep which had been grazing
20 died in a short period of time. The situation was care-
21 fully analyzed by the Italian government operation in
22 that area, and it turned out that these 200 sheep were
23 part of a flock that had been brought from some great dis-
24 tance to graze-- I don't know whether they were being
25 brought to market or exactly what.

1 But anyway, they had stopped off in Seveso, and
2 because some of the area has been restricted in terms of
3 farming, there was a very lush field of grain and grass,
4 and so the sheep dined copiously on this and all got the
5 bloat. Apparently this is a common occurrence under
6 these circumstances.

7 Sixty some odd sheep were autopsied. They
8 actually analyzed the livers of these sheep and found no
9 dioxin. It was interesting getting that information.

10 One thing I should have mentioned: On the
11 human effects, observations in man section of the con-
12 ference, I was hoping that we would get some rather defini-
13 tive information on Seveso. There were three or four
14 reports on the early experience in Seveso.

15 As a matter of fact, there was a dermatologist
16 from England, Dr. Crow, who presented some beautiful
17 slides and gave a very learned discussion on chloracne
18 and described the incidence of chloracne among especially
19 children in Seveso.

20 There are two or three commissions working on
21 studying and following the human effects. They reported
22 very early fragmentary information. But it's interesting
23 that they have expressed and are looking at many of the
24 same concerns that we are in this country, and particu-
25 larly birth defects and incidence of cancer. Their very

1 preliminary impression is that there is no significant increase
2 in the incidence of cancer or birth defects, but they quickly
3 admit that it's still very early to tell. The Seveso incident
4 occurred only four years ago, and so that their epidemiological
5 data is still not collected and analyzed. They were pre-
6 senting some preliminary reports, and we'll be following that
7 course very, very closely.

8 Well, let's move on. We have some reports on updates
9 of VA activities which we'll discuss briefly. On the subject
10 of our literature analysis that was mandated by Public Law
11 96-151, we have had a number of proposals to the request pro-
12 posal. We have reviewed these proposals and have selected the
13 top three and our contracting office is now reviewing those.
14 Hopefully, we will have a contractor selected in the next
15 two to three weeks so that we can proceed with that analysis.

16 I expect it will probably take several months to
17 complete, but we are anxious, of course, to see it under way.

18 DR. MURPHY: Can you tell us who the top three are?

19 DR. SHEPARD: I think that is privileged information
20 for the time being. I am not sure whether they have been
21 contacted yet. I hope they have. I think that information
22 will be out very soon.

23 DR. LINGEMAN: Dr. Shepard?

24 DR. SHEPARD: Yes.

25 DR. LINGEMAN: Dr. Kraybill was the one who served on

12.

1 this committee, and can you tell us who else served on this
2 committee?

3 DR. SHEPARD: Yes, Dr. Robert Miller, Dr. Adrian
4 Gross, and a research librarian from the National Library of
5 Medicine, Joan Burnside.

6 Any other questions on that?

7 I will ask Dr. Hobson to bring us up-to-date on
8 the epidemiological study.

9 DR. HOBSON:

10

11

12

13

14

15

16

Since most of you know the story of this epidemiology
study I will review it extremely briefly for those of you who
do not. The same Public Law 96-151, mandated the VA to con-
duct an epidemiological study of the effects of phenoxy herbi-
cides in Vietnam.

17

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The Request for Proposal was issued. We received
bids under it. The technical selection of the successful
candidate was made, and before the actual negotiation began
the matter was referred to the General Accounting Office which
is now in the process of considering it. The best estimate
we have of the date at which that consideration will be com-
pleted is sometime around December 1st or the middle of
December. The sooner the better so far as we are concerned.
We would like to proceed with the negotiation of the contract

1 and get the design of the study under way.

2 DR. SHEPARD: I failed to mention that Dr. Hobson
3 has now joined our office, and we are most pleased to have him
4 as a member of our team.

5 Next I would like to call on another member of our
6 staff -- Excuse me, I'm sorry.

7 MR. DeYOUNG: Am I to understand, then, that when
8 the GAO finishes in December that the VA will -- the contractor
9 will pick it up and begin work then?

10 DR. SHEPARD: Hopefully so, yes.

11 MR. DeYOUNG: Well, we have to negotiate it with him.

12 DR. HOBSON: That's not the final step in the process.

13 MR. DeYOUNG: Do you have any projection for a start date?

14 DR. SHEPARD: We have stopped guessing.

15 MR. DeYOUNG: In 1981?

16 DR. SHEPARD: Hopefully. That is for the design of
17 the study now. We have to keep making that distinction. This
18 contract is for the design of the study, not the conduct of
19 the study. We have to have a design before we have a study.

20 Any other questions on the epidemiological study?

21 Okay. I would like next to introduce another member
22 of our staff, Miss Nancy Zanis, who will bring you up to date
23 on the Agent Orange Registry.

24 MISS ZANIS: All of the VA Medical Centers and Out-
25 patient Clinics quarterly send us a copy of the Agent Orange

1 exam and the Agent Orange code sheet for each veteran that is
2 examined. The information is sent to my office and we collect
3 it and send it to the Department of Justice for use in the
4 litigation cases that are going on.

5 In October we sent them 52 boxes of these documents,
6 and we plan to send them quarterly shipments as we receive
7 them.

8 The Medical Centers and Outpatient Clinics also
9 send us quarterly a copy of the code sheet on the veteran.
10 These code sheets are sent to the Medical Administration
11 Service here in Central Office. The code sheets are reviewed
12 for accuracy and completeness and then are mailed to the
13 St. Paul Data Processing Center where they are input into the
14 Agent Orange Registry.

15 There are approximately 16,000 records in the
16 Registry at this time. We are currently working on updating
17 the circulars and instructions dealing with the Agent Orange
18 issues. We are also working on a follow-up questionnaire which
19 will be sent to the veteran, all the veterans in the Registry.
20 These questionnaires will request his current address and we
21 will also ask him some general medical questions. The infor-
22 mation will be returned to us and we will input this into the
23 Registry data.

24 DR. GROSS: That is 16,000 records, not 16,000
25 claims.

1 MISS ZANIS: 16,000 records.

2 DR. GROSS: How many claims would that be roughly?

3 MISS ZANIS: I am not sure.

4 DR. SHEPARD: This doesn't have anything to do with
5 claims, Dr. Gross.

6 DR. GROSS: Not claims. I mean persons --

7 DR. SHEPARD: Yes, approximately -- in excess of
8 30,000 individuals who have been examined, there is a lag time
9 between conducting the examination and actually getting that
10 information into the data file.

11

12 DR. GROSS: All right, sir.

13 DR. SHEPARD: Any other questions on the Registry?

14 QUESTION: Would you clarify what you mean when you
15 say "sent to the Department of Justice for purposes of
16 litigation?" I don't understand what you mean.

17 MISS ZANIS: We just box up all of the Agent Orange
18 documents that we receive here (code sheets, questionnaires,
19 and medical documents) and supply the Department of Justice
20 with copies of that material. They have to make them available
21 to the attorneys.

22

23

24 DR. SHEPARD: Yes, Dr. Murphy?

25 DR. MURPHY: Has the VA or Congress or anybody

1 allocated any additional funds to the hospitals and the
2 environmental medicine or environmental physicians for staffing
3 or updating the staff to handle both the increased load that --
4 incoming patients as well as the question of follow-up which
5 we hear so often is something that the veterans are displeased
6 with? Has there been any assistance to the hospitals in the
7 field?

8 DR. SHEPARD: No. The hospital --

9 DR. MURPHY: Anybody working -- I gave you that --
10 I've got a very vocal one in Houston that keeps asking me.

11 DR. SHEPARD: To date no additional resources either
12 monetary or personnel resources have been allocated to the
13 medical centers for the purpose of carrying out this effort.
14 It has been thought that when you look at each facility,
15 although we have had a total of 30,000 examinations, with
16 the exception of a few stations in which there has been con-
17 siderable activity, Minnesota, for example, the actual number
18 of exams is somewhere between 1 and 200, maybe up to 300 in
19 some of the busier places, so that it has not been a major
20 impact on any one medical facility.

21
22
23
24 That is not to say that there is not some substance
25 to the fact that this has been a task that has been laid on to

1 our facilities without additional resources, and, therefore,
2 there may be some concern. I think that as time goes on, well,
3 let me say that we are looking into the impact in certain
4 medical centers and there are a number of medical centers who
5 which have expressed concern and so forth. So we are looking
6 into the issue of whether or not additional resources need to
7 be allocated in order to continue the efforts of the Registry,
8 but so far I think that resources have not produced -- or lack
9 of additional resources have not produced a significant nega-
10 tive impact on the process.

11 DR. FITZGERALD: Dr. Shepard, perhaps I could help
12 Dr. Murphy. The VA in its budgeting does not budget by line
13 item, and as such, the hospital has significant control over
14 the utilization of its entire budget, and they will utilize
15 their budget, I'm sure, wisely as far as the needs for any
16 given time in the institution.

17 DR. MURPHY: Well, that is a good point, and it had
18 occurred to me that maybe the solution was not an
19 increase allocation, but a reallocation of resources.
20 and I have a very limited exposure to that, but I have the im-
21 pression that that is not so easily accomplished. You have
22 one environmental position responsible for this who in probably
23 most cases, hasn't much background in this area. The physician
24 has had to reeducate him or herself, has no additional staff,
25 and sometimes perhaps really gets cut short in being able to accomplish

1 what they themselves in their own conscience feel is a good
2 job in response to that.

3 I, for one, would like to go on record as recommending
4 that perhaps this office do what they can to encourage the
5 chiefs of hospitals of whoever to look into the needs of these
6 environmental physicians.

7 DR. SHEPARD: Yes, certainly that has and is a
8 continuing process. We are making every effort to encourage,
9 guide, what have you, motivate Directors and other responsible
10 individuals in our medical facilities to provide all the
11 available support to this effort. We, of course, here
12 Central Office are providing information, and are maintaining
13 contact. We get many calls from environmental physicians,
14 and I hope are providing the support that they need.

15 If anybody knows or has some evidence to the con-
16 trary, we would certainly like to know about it.

17 DR. MURPHY: Well, in that vein I would like to add
18 one more thing to the record. Henry Cromwell, a physician in
19 Houston, has called me and I have referred him to you. He
20 has recently said that he has received information and thanked
21 me although I deserve no thanks for helping him get this, but
22 I think he is wrong. I didn't really help him. You did.

23 DR. SHEPARD: Well, you encouraged him to call.

24 DR. MURPHY: He appreciated all that.

25 DR. SHEPARD: Fine. Thank you, Dr. Murphy. Any

1 other comments? Yes?

2 MR. DeYOUNG: I have some questions concerning the
3 Registry, Mr. Chairman.

4 DR. SHEPARD: Yes.

5 MR. DeYOUNG: The Registry in the field is kind of
6 a sore point. I want to clarify this because some of my
7 questions may strike you as impertinent otherwise.

8 The VA is professing or holding up the Registry as
9 one of the prime objectives of the Agent Orange research, and
10 as such, I am concerned about its efficiency and the speed and
11 accuracy with which it is going to give us answers.

12 If I have got my figures correct we are talking
13 about 30,000 plus exams now nation wide, around 16,000 of
14 which are currently codified and computer manipulable if that
15 is the right word. Is that correct, that a little over 50
16 percent are not in computer form?

17 DR. SHEPARD: Close to that, yes.

18 MR. DeYOUNG: What is the story on the rest, the
19 other 14 and some thousand?

20 DR. SHEPARD: Let me just correct what may be a
21 misconception on the Registry. I've said this many times,
22 but I guess it bears repeating. The Registry is in no way to
23 be considered a research tool. Okay? The Registry is an
24 effort to identify those Vietnam veterans who are concerned
25 about their exposure to Agent Orange and its possible health

1 effects, and that is all the Registry really is.

2 Now, in the process of doing an examination and
3 asking the veterans to answer questions, obviously there is
4 information generated in that process. That information is
5 being fed into a computer data bank in order to enable us to
6 look at what kinds of problems the veterans are experiencing,
7 their symptomatology, and, hopefully, to come up with some
8 description of the state of health of these individuals. But
9 beyond that, we cannot make any claim that this is in any way
10 a part of an epidemiological study or really any kind of a
11 research effort other than to say that we are interested in
12 finding out what kinds of problems these veterans are
13 experiencing and take a look at their health problems.

14 Another important purpose of the Registry is that
15 it will provide a mechanism for getting back to these veterans and calling
16 them in for further study, further examination, information sharing, and that
17 kind of thing, as scientific evidence is accumulated from other sources.

18
19 We do have or we are developing a description now
20 of some of the information that I alluded to.

21 MR. DeYOUNG: Will you wait until the 30,000 are
22 complete before you begin to get a picture out or will you
23 process the 16,000 some that are in there already?

24 DR. SHEPARD: We are getting reports on the ones
25 that are now in the computer bank. By virtue of the fact that

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1 the information is rather general in nature, it's difficult to
2 make any conclusions as to the types of physical findings or
3 abnormalities, that are being encountered. We are taking a
4 look. In other words, we have a description of groupings of
5 physical problems. We are not trying to get more detail in
6 terms of what exactly those problems are.

7 MR. DeYOUNG: Okay.

8 DR. SHEPARD: We can tell you what percentage of the
9 group has complained of what kinds of symptoms.

10 MR. DeYOUNG: This strikes me as essentially the
11 same thing that the Task Force members did informally two and
12 almost three years ago which is to take reports of the
13 symptomatology and signs and so forth from the veterans and
14 simply write this down and count recurrences and so forth.
15 That is what we are talking about, so it is not hard research
16 in the sense that the National Cancer Institute would
17 recognize.

18 But even so, I mean assuming
19 that it is even for the moment garbage, when will some
20 pictures begin to emerge from this, when will we begin to see
21 a computer profile coming out here?

22 DR. SHEPARD: Well, as I say, we are working -- I
23 can't, if you want a date as to when this will be accomplished,
24 it is an ongoing process. There isn't a finite termination date.
25 This is an ongoing process.

1 The reason for the lag between the 30,000 examinees
2 and the 16,000 that are in the computer is it takes a while to
3 encode this information, to edit it, make sure we don't have
4 repetitious information, and get it into the computer in a
5 form that can be retrieved.

6 I would think that in the not-too-distant future we
7 will be coming out with a description of what we have
8 in the computer file now. We are
9 working on accumulating that information. We are beginning
10 to get reports in, and I think before long we will come out
11 with a simple statement as to a description of that. Any
12 other questions on the Registry?

13 MR. DeYOUNG: Excuse me. It is my understanding
14 that there is a new form being generated to save the step of
15 hand coding. Is that correct? Where does that stand right
16 now? As I understand it, right now you are generating two
17 sets of documents, one that is being done at a local level
18 at the RO, and then that is being converted to a coding form
19 for the computer use. Now, I had heard some rumors to the
20 effect that a new form was being created which would mesh
21 those two and eliminate a step and, thereby, speed up the
22 process. Is that correct?

23 DR. SHEPARD: Okay. What we are going now because
24 we have learned a lot from what has already happened. Some of
25 the things that we have learned are that many veterans don't

1 have very accurate information on their exposure. The useful
2 information, the physical finding kind of information, the
3 objective findings that physicians examining these veterans
4 have noted, is not being encoded in a readily usable form, so
5 we are going back to do a major revision of the Registry in
6 order to make the information more usable and also -- in other
7 words, ask the questions that we think we can get answers to
8 and get more usable medical information into the computer so
9 we can then analyze it, evaluate it, not analyze it, but
10 retrieve it more directly. I think there is a rather indirect
11 process that we have to go through in order to retrieve
12 detailed information.

13 MR. DeYOUNG: Will there be any reexamination of
14 veterans necessary for that or is it all compiled?

15 DR. SHEPARD: No, I don't think -- see, the basic
16 process will not change. A questionnaire will be answered.
17 A physical examination will be done. A base-line group of
18 laboratory studies will be done. So that process need not be
19 changed. The processes of that part of the process is fine.
20 The part of the process that isn't fine is how that information
21 gets encoded, how it gets put into the computer bank, and
22 the usefulness of it and its retrieval process.
23 That is the thing that is going to be changed. *

24 MR. DeYOUNG: Will the 16,000 that have already been
25 processed be reworked in the light of this new method or will

1 they be handled as they are right now?

2 DR. SHEPARD: We will hope that we will not have to
3 reexamine the veterans. We hope we will not have to bring
4 them back for a reexamination. We hope that the information
5 that is currently in the record can be reworked in such a way
6 as to be encoded properly using the new format. That is one
7 of the points we are going to be looking at very closely to
8 see what is there now and how that can be reworked in order to
9 make the information more useful.

10 MR. DeYOUNG: Thank you.

11 DR. MURPHY: You mentioned that Minnesota was
12 different than the rest of them and you said you had --

13 DR. SHEPARD: Right. Okay. The state of Minnesota
14 decided to organize an outreach program and contact virtually
15 every -- attempt to contact virtually every Vietnam veteran
16 in the state. This was helped by the fact that Minnesota
17 provided a bonus to Vietnam veterans. The bonus list promoted
18 the organizing of cities, counties, and towns for this effort.
19 The other factor that made this state exceptional was the fact that in
20 Minnesota apparently there is a very strong, well-coordinated, group of
21 veterans' organizations and apparently a higher representation of Vietnam
22 veterans in the traditional service organizations than exists elsewhere
23 in the country. That combination of factors enabled the state to organize
24 an outreach program which resulted in several thousand Vietnam veterans
25 applying for the examination at our hospital in Minneapolis.

1
2 That is why a hospital in Minneapolis has many more
3 examinees on their records than the other hospitals. It
4 simply was an outreach program that was initiated by the
5 state in conjunction with the veterans' groups.

6 Now I have heard rumors to the effect that other
7 states are thinking about doing a similar effort. I was
8 recently out in California, and I understand that there is a
9 movement afoot to initiate a similar program in the state of
10 California. We hope to stay ahead of that in order for us to
11 be prepared to handle these veterans in our medical facility
12 in a smooth and expeditious way.

13 I must congratulate the hospital in Minneapolis for
14 taking on a tremendous workload without very much advance
15 warning, and they really did a superb job.

16 MR. DeYOUNG: One final thing on the Registry,
17 please, Dr. Shepard. Could the Committee be provided with
18 copies of the working papers of the Registry, samples and so
19 forth of the codifications and the exam forms and such?

20 DR. SHEPARD: Yes, we plan to before we reach any-
21 where near a complete revision, we plan to discuss it with
22 this Committee and representatives of veterans' organizations
23 and involve them in the process of the formulation, definitely.

24 MR. DeYOUNG: Thank you.

25 DR. SHEPARD: Well, let's move on. Donald Rosenblum,

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1 also on our staff, will mention a new initiative of our office,
2 namely the Agent Orange Bulletin, which we had hoped to have
3 ready at this time. Mr. Rosenblum.

start 1B 4 MR. ROSENBLUM: Thank you, Dr. Shepard. The Agent
5 Orange Bulletin has been established primarily to provide
6 environmental physicians and other medical staff at VA instal-
7 lations with information regarding the recent developments
8 concerning herbicide orange and related matters. Copies will
9 also be made available on an individual request basis to other
10 interested parties. A copy will be sent to all Advisory
11 Committee members.

12 The first issue of the Bulletin will soon be avail-
13 able. It will include articles concerning the VA's response
14 to the Agent Orange matter, namely, the establishment of the
15 Office of Special Assistant to the Chief Medical Director for
16 Environmental Medicine headed by Dr. Shepard, the Policy
17 Coordinating Committee chaired by VA General Counsel Guy
18 McMichaels, this Committee, our Data Analysis and Chloracne
19 Task Forces, and the Agent Orange pamphlet and videotapes.

20 The first issue also contains the analysis of the
21 European studies by Dr. Hobson, some Agent Orange examination
22 statistics, library notes, a calendar of events, and an
23 article concerning progress in the epidemiological study, and
24 literature review.

25 Comments, criticisms, and articles from environmental

1 physicians and other interested staff members are encouraged.
2 We would also be delighted to receive input from members of
3 this Committee.

4 Material should be sent to me, Donald Rosenblum,
5 Mail Symbol 102, VA Central Office, Washington, D.C. 20420.
6 The Bulletin will be published on a periodic basis approxi-
7 mately once every two months. Thank you.

8 DR. SHEPARD: Any questions on the Bulletin? We had
9 hoped to have one ready for this meeting, but it's just short
10 of that, but we are encouraged that it will be coming out
11 very soon.

12 MR. ROSENBLUM: Very soon. Thank you.

13 DR. SHEPARD: Okay, Mr. Layne Drash will bring us up-
14 to-date on the progress of the videotape.

15 MR. DRASH: Thank you, Dr. Shepard. Good morning,
16 everyone. Very quickly I would like to give you a rundown of
17 what we are doing in regards to our educational efforts, not
18 only for Vietnam veterans and their families and the general
19 public, but also educational videotapes or films with which we
20 can educate our health care staff, including our environmental
21 health care physicians and dermatologists and whatever staff
22 are concerned with working with veterans coming in for the
23 Agent Orange exams.

24 We are actually speaking in terms of two videotapes.
25 The first one is in the final stages of preparation. On

1 October the 16th an unedited copy was shown to the Administra-
2 tor and to members of the Central Office staff in which they
3 reviewed it, made comments, and at which time the suggestion
4 came up from the Administrator that we should share this with
5 the major service organizations for their comments and review
6 and suggested changes.

7 Consequently, on October 26th, I believe, the
8 service organization representatives did meet in Central
9 Office and reviewed the videotapes and provided comments to
10 the VA, and some of these recommended changes have been put
11 into the particular film that was reviewed at that time. The
12 film that was reviewed was the one that was made to be shown
13 to the veterans and the public. It provides a very brief
14 overview of the utilization of Agent Orange in the Southeast
15 Theater of Operations including Vietnam and gives a rundown on
16 many of the VA's activities, including the Agent Orange
17 Registry in dealing with this very complex issue.

18 We are looking for a target date of around the first
19 week in December in having this particular tape ready for
20 distribution to the field. Our distribution of the video-
21 tape as we see it now and this was discussed only yesterday in
22 the Policy Coordinating Committee, again chaired by Mr. Guy
23 McMichael, General Counsel. The distribution, as we see it,
24 would be -- we would provide one copy to each of our 172 VA
25 Medical Centers, 1 copy to each of our 8 independent Outpatient

1 Clinics, 1 copy to each of our 91 Outreach Centers, and we will
2 maintain copies here in Central Office for utilization by
3 service organizations and the general public, and we will be
4 providing probably 1 copy to each of the 57 VA Regional
5 Offices that are scattered throughout the nation.

6 I won't go into the details of the film too much. I
7 believe Mr. DeYoung is going to discuss that during his part of
8 the program.

9 The second videotape that we are talking about is
10 really in the conceptual stages at this point. It is a much
11 more difficult film to put together because it will be utilized
12 for the training of our environmental physicians and our
13 dermatologists. Consequently, we have to take a different
14 approach in preparing this since it will be a staff training
15 instrument.

16 It may be more than one videotape. It may be some-
17 thing that is supported by written materials to support the
18 program that is presented. We are looking -- we don't have
19 a target date really for that film, but we are starting to
20 work on it at this point with the Regional Medical Education
21 Center in St. Louis, and I would anticipate that it would
22 probably take about a year, give or take a couple months, for
23 a final unedited copy to be ready for review.

24 I would be glad to answer any questions you might
25 have on either of the films.

1 MR. ENSIGN: I'm curious if you have any plans to
2 utilize public service types of commercial television cable
3 networks around the country to show this film. Have you
4 thought about that?

5 MR. DRASH: Yes, when we distribute these to our
6 field facilities we would anticipate that they would utilize
7 it for public service ^{announcements} / or what have you. We have
8 built within the first videotape that we prepared the potential
9 for commercial breaks, so it could be utilized for that
10 purpose. We are encouraging that the videotapes for the
11 veterans be utilized within the areas of our Outpatient
12 Clinics where they can be shown either upon request or they
13 can be put on a continuing rotating basis for showing to
14 the people that come into the Outpatient Clinic. Then it
15 will ^{also} be available by virtue of anyone writing into the VA
16 Central Office and requesting to see it.

17 So it will be available to the media. It will be
18 available to the general public, and what have you. Any
19 other questions? Thank you.

20 DR. SHEPARD: I might just add that we definitely
21 would encourage use by the media. In fact, the film has been
22 structured so that it can be readily used by the media, so we
23 are hoping that that will occur.

24 And I would also like to announce that we are going
25 to show the tape at the close of this session, so you'll see

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1 in your programs at 11:30 we'll be showing the tape.

2 Any other questions?

3 I see they have turned the heat on. I hope we will
4 thaw out shortly.

5 Next I would like to call on Dr. Carolyn Lingeman
6 from the Armed Forces Institute of Pathology and the National
7 Cancer Institute to discuss the status of the AFIP registry
8 and also review the protocol for the soft tissue
9 sarcoma study that is being proposed. Carolyn?

10 DR. LINGEMAN: We will discuss these together
11 because they are both involved in the same set of materials.
12 I would like to start off by saying that maybe there are some
13 people who do not know what the AFIP is. The Armed
14 Forces Institute of Pathology (AFIP) / ^{was founded} more than 100 years ago
15 by the Army,

16 The purpose was to collect and review
17 materials from Civil War casualties to
18 better learn to prevent and cure diseases that were responsible
19 for these casualties. In those days many deaths were due to
20 tetanus, malaria, and other infectious diseases that took
21 more lives than the acute battle wounds

22 So it is very fitting, I think, that more than 100
23 years later, the AFIP resources are still available and
24 can be used to combat the new horrors of modern warfare,
25 namely the chemicals. The AFIP now has nearly 2 million accessions in its
33 registries.

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1 The AFIP Registry listed on the program is a pathology registry which
2 was started by Dr. Nelson Irey who is Chairman of the Department of Envir-
3 onmental and Drug-Induced Pathology at the AFIP. This is one of the newest
4 registries. There are 33 registries in all.

5 Most of the AFIP registries are devoted to single organ sites. For
6 example, there is a Registry of Hepatic Pathology for liver diseases.
7 There is another registry devoted to the diseases of the lung. There is
8 also one for soft tissues. Dr. Irey's registry, which is about four years
9 old, was formed to collect material from people who believe that they had
10 been exposed to environmental agents. Two years ago Dr. Irey began the
11 Agent Orange Pathology Registry to collect material specifically from
12 Vietnam veterans who believed that they had been exposed to herbicides.

13 Presently there are only about 90 accessions in the Special Agent
14 Orange Pathology Registry. We hope to find out ways to improve the commu-
15 nications with the pathologists or whatever we have to do to get more
16 material in.
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1 About 40 percent of all AFIP accessions come from service hospitals,
2 Air Force, Navy, and Army hospitals all over the world. Sixty percent are
3 from civilian sources. So there is quite a collection of materials to be
4 studied and quite a bit of individual expertise among pathologists on the
5 staff.

6 I have the opportunity to utilize the materials, to do some of the
7 cancer studies.

8 With Dr. Shepard's help I hope to go through the records in the VA's
9 Agent Orange Registry to identify the cancer patients and see if we can
10 get biopsies from all of these patients sent to the AFIP for review.

11 Many epidemiologic studies are hampered by lack of consistent pathol-
12 ogy diagnoses.

13 DR. MURPHY: I would just like to ask, the is Dr. Ireys -- is that
14 right, Ireys?

15 DR. LINGEMAN: Dr. Nelson Ireys.

16 DR. MURPHY: And that is the AFIP Registry setup specifically for
17 suspicion of chemical-induced disease, do I understand that?

18 DR. LINGEMAN: There are actually two registries
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involved. One is the Registry of Environmental Pathology. The other is the Agent Orange Pathology Registry, which is actually part of the Environmental Pathology Registry.

DR. MURPHY: But that only has 90 entries, is that --

DR. LINGEMAN: ^{the Agent Orange Pathology Registry has} So far / only has 90 entries.

DR. MURPHY: Does this -- you mentioned biopsy.

What effort has there been to particularly focus on dermatoses of various kinds? I got a question from one of our physicians who reads the minutes of these meetings. About two meetings ago -- I've forgotten the names of the principals involved -- but there was a recommendation that people report and send in biopsy materials related to various dermatoses. I am sorry I can't be more specific than that.

He was questioning me about who takes these -- where can I get the information -- is this the Registry that would receive that or is Dr. Irey the person that needs to be contacted?

DR. LINGEMAN: Yes.

The reason I say approximately ⁹⁰ is because some are not completed. The Registry is continually being updated. We have had several skin biopsies from Vietnam veterans but none are chloracne.

But the average dermatologic lesion that is seen at the VA hospitals does not warrant a procedure like a

1 biopsy. Only severe lesions would be biopsied. Most of the time
2 this would not be done unless maybe there was a suspicion that
3 it was chloracne.

4 When Dr. Irey receives a skin biopsy he routinely sends it
5 to the Department of Dermopathology where
6 we have a group of pathologists who specialize in diseases of
7 the skin examined it. The diagnoses are made by pathologists with / great experience in diseases of the skin
8 It is possible that some skin / biopsies may have gone to the
9 Skin Registry / directly without our knowing about them. We are con-
10 stantly working within the AFIP to alert
11 pathologists in / the other departments about our interest in material from patients who
12 may have been exposed to chemical,
13
14

15 DR. SHEPARD: Yes. In that connection, Carolyn, I
16 think that we need to redouble our efforts to contact all --
17 certainly all -- military hospitals and all civilian hospitals
18 to encourage them to identify Vietnam veterans and send either
19 surgical or autopsy materials to the AFIP. In conjunction or
20 in connection with that effort we have taken some steps. We
21 have reissued our VA circular on the subject. We have made
22 it the subject of a recent hot-line discussion with all of our
23 medical facilities. In addition, we have asked the Department
24 of Defense to request that the word be reemphasized to all
25 military hospitals and it is my understanding that a memorandum

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1 has gone out from the Secretary of Defense or the Undersecre-
2 tary of Defense for Health Affairs to all three Surgeons
3 General for dissemination to all military hospitals, and I
4 hope we will begin to see some reflection of that.

5 So we will continue to encourage all medical facili-
6 ties, be they Federal or non-Federal to send in and identify
7 Vietnam veterans and make these materials available to the
8 AFIP for their review and to be entered into the Registry.

9 Yes, Dr. Gross?

10 DR. GROSS: I would just like to make a comment.
11 Dr. Lingeman is much too modest to mention that the AFIP is
12 probably the finest pathology institution in the world as far
13 as competence, material. Every pathologist is practically
14 busting his or her tail end to spend a period of study there,
15 education, looking at this tremendous collection.

16 Another question, Dr. Lingeman. Is there available
17 in the Registry material on experimental animal studies that
18 have been involved in dioxine phenoxy herbicides or is that
19 in the veterinary, and if so, what is the connection? Do you
20 plan to access experimental materials?

21 DR. LINGEMAN: We will try to get some of this
22 material. In fact, we hope that the National Cancer Institute
23 will eventually make the AFIP its final repository for all
24 experimental work that its bioassay program has done. This is
25 what I would like to see done. At the present time this

1 material is housed in a different facility and it is considered
2 privileged information, but eventually we would like to see
3 that happen.

4 There is a very active veterinary pathology registry
5 which interestingly was formed to take care of the horses when
6 the cavalry was the big thing, and it sort of changed its
7 pitch over a period of time too.

8 DR. GROSS: There are military dogs now and --

9 DR. LINGEMAN: Right, military dogs. All the
10 materials, by the way, from the military dogs are there and
11 available for study and are being studied. There is a yearly
12 report that goes out from the Veterinary Pathology Department.

13 I would like to say that I am not being modest at
14 all , Dr. Gross, because I am paid by the NIH and I have
15 the privilege of working at the AFIP , so I will agree with you.
16 This is a world-renowned institute of very fine pathologists
17 who are recognized everywhere.

18 DR. SHEPARD: Any other questions on it? Yes, sir.

19 MR. DeYOUNG: Yes, just for clarification, now. I
20 understand that -- if I understand this correctly, all biopsy
21 material now from VA institutions is automatically forwarded
22 for a Vietnam veteran, is that correct? Or is there some
23 identifier that is being used?

24 DR. SHEPARD: Any Vietnam veteran who undergoes a
25 surgical procedure or who dies in a VA facility and on whom an

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1 autopsy is performed, each one of those medical facilities is
2 being directed to send material to the AFIP. Now, when you
3 say automatic, nothing is automatic.

4 MR. DeYOUNG: Well -- I understand.

5 DR. SHEPARD: But, obviously, there are several
6 human factors involved, and so we are trying to -- as I say we
7 are redoubling our efforts to try and make sure that all such
8 materials do get forwarded to the AFIP.

9 MR. DeYOUNG: Is it standard procedure, then, for
10 all cancer biopsies to be forwarded to AFIP for a Vietnam
11 veteran, living or deceased?

12 DR. SHEPARD: That would be included in a surgical
13 procedure, so biopsy material, autopsy material --

14 MR. DeYOUNG: We had mentioned autopsy, but I wasn't
15 sure about surviving those.

16 DR. SHEPARD: Right, surgical material.

17 DR. LINGEMAN: Dr. Shepard, isn't it true that as
18 part of the VA's pathology quality control program -- that a certain
19 percent of biopsies and autopsies from all the VA hospitals are sent
20 automatically to the AFIP?

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23 DR. SHEPARD: I am not sure of that detail.

24 DR. HOBSON: That is true. That is part of the
25 quality control of the pathology work done in the Veterans'

1 Administration. I don't know the details of it, but the material is sent
2 routinely to the AFIP for checking on the VA pathologists.

3 DR. LINGEMAN: I think a certain percent are sent. Usually if a case
4 is not identified as an Agent Orange case, we may not see it. We have a
5 problem with the medical profession as a whole because in the average
6 medical history, an environmental history is not taken very well, if at
7 all. Once in a while the patient's occupation will be asked, but often
8 it is not. I think we have a big job to educate the medical profession
9 starting with students in medical school, to get the physicians in the
10 habit of asking about the occupational history. Usually when a request
11 is made to a pathologist to give a diagnosis on a biopsy, there is not
12 much history given. We would like to get the surgeons in the habit of put-
ting the environmental history on the pathology request form.

13 Some think that the pathologist does a better job if he makes a diag-
14 nosis without knowing the history. Maybe he can be more objective if he is
15 looking at the slide and saying, "I think it's cancer," or "I think it
16 isn't," without being influenced by the fact that it is an Agent Orange
17 case. I don't know.

18 DR. SHEPARD: Yes, sir.

19 MR. ENSIGN: I want to be sure I understand. Then
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1 any Vietnam veteran who develops a malignancy or has a biopsy
2 taken, this Institute would be interested in receiving material
3 from that person's physician in some way? That is known as
4 the policy you are trying to engender?

5 DR. LINGEMAN: Right. I think that many
6 of these biopsies are being done in civilian hospitals, and I
7 think this is something maybe the veterans themselves should
8 be acquainted with so that they can ask their doctor to ask
9 the pathologist in that private hospital to send / ^{the biopsy} to the
10 AFIP should be earmarked to go to the Special ^{Pathology} /
11 Registry. Otherwise, it will go to the Accession Depart-
12 ment, and if it is a liver case, it will go to the Liver
13 Registry and so on. If
14 perhaps the veterans' groups themselves could publicize
15 this just a little bit it would be helpful.

16 DR. SHEPARD: Another question I haven't been quite
17 clear on, Carolyn, where actually should it be sent in the
18 AFIP, to the Department of Environmental Pathology?

19 ^{be labeled:}
20 DR. LINGEMAN: Yes, it should/Attention, Agent Orange
21 Registry.

22 DR. SHEPARD: Thank you.

23 DR. GROSS: Would you want all these things to come
24 to you routinely even if nobody suspected exposure to Agent
25 Orange? You would be flooded with material there.

DR. LINGEMAN: Well --

1 COL. HODDER: That's what we want.

2 DR. SHEPARD: That's what they say that want.

3 DR. LINGEMAN: The AFIP is set up to handle huge
4 volumes of material. They have had almost 2 million cases
5 already, and --

6 DR. GROSS: Yeah, but that's in 100 years.

7 DR. LINGEMAN: Right. ^{AFIP is a} The/mass production facility.
8 I don't think there is a fear of being flooded. If it comes
9 to that, I think maybe that would be some impetus to add some
10 new staff. I don't know.

11 DR. SHEPARD: Okay, Carolyn, then, would you like
12 to go on to tell us a little bit about the progress of this
13 soft tissue sarcoma study?

14 DR. LINGEMAN: Okay. I would like to preface that
15 by talking just a little bit about the carcinogenicity of
16 dioxin and herbicides in general. I think it is generally
17 agreed that 2,4-D and 2,4,5-T in themselves are not believed to
18 be carcinogenic, but that they actually have not been too well
19 tested. The tests are inconclusive..

20 However, we do have evidence that TCDD itself is a
21 carcinogen in rats and mice

22 in several body systems when given orally. The National
23 Cancer Institute, under contract to a private organization, is
24 in the final stages of preparing reports on two studies of
25 testing dioxins, both by the dermal and by the oral route.

1 And the final reports are under review, but should be available
2 in a short period of time, and we will make these available to
3 the committee. They will be public information for anybody
4 else who wants them.

5 The preliminary reports
6 confirm the carcinogenicity of TCDD, so that is not an issue.

7 results of mutagenicity studies are somewhat incon-
8 clusive, and I think there is a need for these to be repeated
9 and reevaluated.

10 We have a report by Dr. Henry Pitot which
11 was circulated to the Committee members, a report which
12 appeared in the October 1980 issue of "Cancer Research" review-
13 ing and reporting on some new experiments concerned with the
14 mode of activity of TCDD in its carcinogenic activity. You
15 may be aware that being a carcinogenesis in a human or animal
16 system can involve several different mechanisms. It does not
17 seem from what is known that TCDD acts directly
18 on DNA. It seems to work by a different mechanism and we are
19 not certain what it is. Some experiments reported by
20 Dr. Pitot seem to indicate that possibly TCDD acts as a cancer
21 promoter. This is shown in an experimental system, a two-
22 stage system. In order for TCDD to be carcinogenic, an initiator
23 is required. This means that another chemical or virus or
24 radiation of some cases
25 would be required to act on the DNA first, and, not being

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1 carcinogenic in itself, to make this cell vulnerable to the promoting.
2 activity of dioxin.

3 There are other examples of cancer promoters, including phenobarbital.
4 That is again an experimental system. These are experimental results
5 which cannot be extrapolated directly to human studies. We should however
6 take these experimental observations into consideration in planning the
7 epidemiologic studies. We believe that the carcinogenicity of TCDD re-
8 quires a long period of time rather than a single exposure.

9 If TCDD is a cancer promoter in man, we don't know what the initiator
10 might be, and this is an area for research.

11 I would like to review, then, the types of epidemiologic studies we
12 might wish to do when trying to determine whether TCDD is a carcinogen in
13 man. There are two basic types, the cohort study and the case control
14 study. One good example of a cohort study is that of the Swedish railroad
15 right-of-way workers who have been exposed to a variety of herbicides, in-
16 cluding the phenoxy acids.

17 The problem in a cohort study is that cancer is a relatively common
18 disease and usually has a long incubation period so that long periods of
19 time and large numbers of people are required to provide meaningful results.
20 Unless you encounter an unusual histopathologic type of neoplasm and you
21 don't see the same one in controls, it is frequently difficult to determine
22 whether significant differences exist between the two groups, this is,
23 between the exposed and the non-exposed.

24 If frequent types of cancers such as those of lung or colon or the
25 lymphatic system, sophisticated types of mathematical analyses may be re-
quired to determine if differences exist between the groups, and this is not
always easy.

1 In the case of TCDD it is encouraging to note that in a cohort study
2 of more than 100 men exposed 30 years ago during the industrial accident
3 in Nitro, West Virginia, there were no excess cancers reported. So after
4 30 years that is a significant thing. However, it was a small number of
5 people.

6 Among the 80 or 90 accessions that have been received so far by the
7 AFIP Agent Orange Pathology Registry, relatively few have been neoplasms,
8 and these have been the usual kinds that we would expect in men of this age
9 group. We haven't seen anything yet to suggest an excess of any type of
10 cancer in Vietnam veterans. We will need many, many more cases before any
11 such judgement can be made.

12 I would like to say that we do have some statistics which can tell us
13 how many cancers would be expected in men of various age groups. These
14 have been collected world-wide by several different international organiza-
15 tions. We can predict that in young men, particularly those age 30 to 35,
16 which would be the age group in which most Vietnam veterans are at this
17 time, we can expect so many neoplasms of certain types. Cancer is a very
18 common disease. It occurs at all ages. Men in their 20's and 30's are
19 particularly susceptible to cancers of the lymphatic system and cancers of
20 the testes. We can predict, from records of the Connecticut Tumor Registry
21 that 6 or 7 out of every 100,000 white men ages 30 to 35 will develop neo-
22 plasms of the testes each year, and about half of them will die from the
23 cancer.

24 If we project that figure over 10 years, we can calculate that 65 men
25 of every 100,000 in the age group 30 to 35 would get a neoplasm of the
26 testes in ten years. If we use a cohort of 500,000 men in that age group,
27 325 men would be expected to develop cancers of the testes in 10 years.

1 We can do the same thing for Hodgkin's Disease or for malignant
2 melanomas or any other cancer, so that over a period of time, if we have
3 enough people in the Registry, we can have some idea of how many cancers
4 to expect and we can perform some statistical analyses to see whether the
5 number observed were actually more than expected.

6 The other type of study which we can do is the case control. The
7 AFIP offers a very, very fine repository of cases to do this kind of study.
8 We have decided to do the soft-tissue neoplasm study first for two reasons.
9 One is that there are two reports in from the Swedish literature that an
10 excessive number of people exposed to phenoxy herbicides developed neoplasms
11 of the soft tissues. Second, we were able to negotiate quickly with the
12 Chairman of the Department of Soft Tissue Pathology at the AFIP who has
13 agreed to let us use all the cases which are sent into his registry for
14 consultation. Dr. Enzinger is a world authority on this subject.

15 Soft tissue neoplasms are frequently difficult to diagnose and they
16 are frequently difficult to classify. They involve many different tissues
17 such as muscle, fat, blood vessels, nerves, or connective tissues. We will
18 have an opportunity to see if any one of these locations predominates in
19 Vietnam veterans. We have been asked whether we are going to repeat the
20 Swedish studies. The answer is we are going to try to do it better.

21 Our epidemiologist is a member of the Environmental Epidemiology
22 Branch at the National Cancer Institute. He and his colleagues are pre-
23 paring a questionnaire at the present time, and we hope to have this ready
24 to go within the next few months.

25 We don't know how many soft tissue neoplasms are in the Registry at
the present time, probable several hundred a year, so we probably will have
a significant number to work with. However, some people have pointed out

1 that the time of exposure may not have been long enough. Now, you will
2 recall that in the Swedish studies the time periods between first known
3 exposure to herbicides and onset of a neoplasm ranged from 6 to 27 years.
4 Some of the Vietnam veterans served as early as 1962 and 18 years would
5 have passed. So we may be getting into this latent period.

6 If we don't get significant results in the first phase of the study,
7 this can be extended. We will begin with cases diagnosed between the years
8 1975 to 1980. I think we should point out that soft-tissue neoplasms are
9 very, very malignant neoplasms as a rule, and they kill rapidly, but some
10 patients live a while. We will ask both the patients and the matched con-
11 trols who do not have neoplasms whether or not they were in Vietnam,
12 whether or not they believe they were exposed to herbicides, and whether
13 there were opportunities for exposure to herbicides or other chemicals,
14 carcinogenic chemicals, in the civilian sector .

15 We hope to figure out a way to check these out. If a person gives
16 a positive history we hope to be able to check with the Department of
17 Defense and find out if there is reason to believe that this veteran was
18 in the area in which the herbicides were used. We also hope to be able to
19 check out civilian exposure, and this will not be easy, actually very dif-
20 ficult to do.
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1 I think most of the Committee members have had
2 opportunities to look at the protocol which is still a pre-
3 liminary one, and we will welcome suggestions from anyone as
4 to how this study could best be handled.

5 DR. SHEPARD: Thank you very much, Carolyn.
6 I would like to comment on that that last statement of Carolyn's,
7 that you have been provided copies of the preliminary protocol.
8 Carolyn, I am sure, and I know we would be very interested
9 in receiving comments from any of you who have expertise in
10 this area. Please review that and get back to Carolyn with
11 your comments.

12 Let me just ask a couple ^{of questions} /now. Do you project a time
13 when we will have a completed protocol? Are you trying to
14 develop a more complete protocol detailing some of the --

15 DR. LINGEMAN: Right. We are in the process
16 of developing a more complete protocol, and I hope within the
17 next few months that we can have the final version of the study design
18 for you.

19 DR. SHEPARD: Thank you. Now, we would like to have
20 the opportunity to review that too.

21 DR. LINGEMAN: Before we start the study you will
22 have that opportunity.

23 DR. SHEPARD: I might also suggest that the scien-
24 tific panel of the Interagency Work Group probably would also
25 like to take a look at that.

DR. GROSS: Dr. Lingeman, two things. With reference

1 to whether the exposure was non-military or military, that
2 -- is your object is not necessarily to establish only a
3 cause-effect relationship with military wartime exposure, but
4 any phenoxy herbicide, even if it is compact lately to establish
5 a cause-effect relation, is that correct?

6 DR. LINGEMAN: Yes.

7 DR. GROSS: The other question is on the epidemio-
8 logic study, how do you proceed, either prospectively or
9 retrospectively or both because it makes a great deal of
10 difference as to the number of subjects that you need. If you
11 do a retrospective study, well, you focus on the particular
12 cancer or disease. Then you need much fewer subjects to
13 determine the association, because you in effect ask what
14 is the association with the effect. If you go prospectively
15 you need many thousands as you correctly pointed out.

16 DR. LINGEMAN: The case control study --

17 DR. GROSS: Is a prospective one.

18 DR. LINGEMAN: Well, it is
19 retrospective in that we are taking the patients who have the
20 cancer and saying, "Did you serve in
21 Vietnam? Were you a farmer? Did you ever work for the
22 Forestry Service? Did you ever work for the Highway Depart-
23 ment? What did you do there?

24 DR. GROSS: You tried to establish an association?

25 DR. LINGEMAN: Right, so in that sense it is

1 retrospective.

2 DR. GROSS: I see.

3 DR. LINGEMAN: Now, it is prospective in that as every year we will up-
4 date this and take the newest cases while they are still as near the date
5 of diagnosis as possible. Many of these people are already dead. We will
6 be writing to relatives of many of them rather than to the patients them-
7 selves. The relatives never can give quite as good histories as the
8 patient themselves.

9 The first phase of the study will involve all cases diagnosed between
10 1975 and 1980. After 1980, we will get a computer write-out of the next
11 set of patients that have been diagnosed in each quarter and write to them,
12 and the matched controls at the same time. Concerning the earliest cases,
13 as time goes on, the worse the memory is. Many patients will be lost to
14 follow-up.

15 I think if we keep the study updated quarter by quarter, year by year,
16 then we will get better histories as time goes on. Now, we may be able to
17 get some significant information the first time around and we may not. We
18 may get nothing. We may come up with things that are only marginally
19 significant or we may not be able to answer any questions at all. We will
20 try to continually analyze the results as we go along and continually update
21 them.

22 We plan to then also start a study on the lymphatic system pretty much
23 at the same time as this one, and the study design for that is still under
24 review. As time goes on, if it looks like from the Special Pathology
25 Registry that we are getting an excess of one kind of neoplasm, then we will
start a study of that one also.

Dr. Shepard has mentioned that cancer of the testes might be the next

1 one to study because there is a great deal of interest in them because they
2 occur in young men. Many of the epidemiologic features of these are unknown.
3 Dr. Mostofi of the Genito-Urinary Registry of the AFIP says he is interested
4 in study causes of testes and the bladder.

5 So, as time goes on, I think we should be flexible in our attitude.
6 If it looks like the soft tissues isn't going to yield anything, maybe we
7 should shift gears and emphasize something else. I think this is the value,
8 then, of the cohort study, that it will point out to us that maybe this neo-
9 plasm is unusual and maybe we should look at that one instead or take the
resources and spend more effort on that.

10 DR. SHEPARD: Okay. Thank you, Carolyn. Are there any other questions
11 for Dr. Lingeman? Yes? Dr. Erickson.

12 DR. ERICKSON: In your outline of your study design you say that con-
13 trols are going to be chosen from among accessions, patients who don't have
14 neoplasm diseases. What is the spectral illness types that will be you con-
15 trol?

16 DR. LINGEMAN: I knew you were going to ask that. We plan to use pa-
17 tients whose biopsies were sent to other AFIP Registries. We could limit
18 this to a single Registry such as the Dental Registry, which would be pri-
19 marily gingivitis and relatively non-life-threatening diseases. We have
20 talked about that. There just may not be enough of them.

21 We do not want to include neoplasms of any type. We want to exclude
22 skin lesions. Anything that could be confused with chloracne should be ex-
cluded.

23 A lot of biopsies from well people are sent to the AFIP. I think that
24 some decisions have to be made about what -- how sick should they be, how
25 well should they be. Hepatitis would probably be a poor control because

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herbicides can damage the liver. It would not always be possible to 51.
exclude a chemical as the cause of the hepatitis.

So, we have some very hard decisions to make there.

1 I think the AFIP epidemiologists might also suggest that in
2 addition to "sick" controls whose biopsies are/^{sent to}
3 the AFIP we should also select a group of well controls, maybe
4 through the National Death Registry or one of the other tumor
5 registries. I don't know. What are your suggestions?

6 DR. ERICKSON: It's a complex problem. The NCI often
7 uses a census as set up by telephone scheme. Thereby controls
8 from that census of well people.

9 DR. LINGEMAN: Yes, this is under consideration.

10 We will give it a lot more considera-
11 tion to that before the final decision is made.

12 DR. GROSS: But commenting in relation to that, I
13 think probably you would want your control to reflect closely
14 a population of veterans who are generally in better health
15 than the general population. They are examined initially to
16 be inducted into the Armed Forces, drafted, whatever, and so
17 probably the general level of health in veterans is superior
18 to what you would find in the Connecticut Tumor Registry even
19 if you match by age.

20 You would want something quite comparable to the
21 veteran, not only in age, but in being in the military service
22 in the first place.

23 DR. LINGEMAN: Well, I think we probably will end up
24 with veterans both who have cancers who have served in Vietnam
25 and those which have not which are sort of built in controls.

1 We are going to include women as well as men, so that will be
2 another set of controls. Women with the same kinds of neo-
3 plasms who have probably not served in Vietnam. I think very
4 few women were in Vietnam.

5 DR. GROSS: Yes. It will be difficult to get many
6 cancers of the testes in them.

7 DR. LINGEMAN: No, you certainly wouldn't.

8 DR. HOBSON: Do you intend in selecting your controls
9 to match deceased with deceased controls and living with
10 living controls?

11 DR. LINGEMAN: Yes, we will get reports
12 from relatives of those who are deceased as opposed to --

13 DR. HOBSON: Right.

14 DR. LINGEMAN: Right. We have taken that --

15 DR. HOBSON: I gather from your little brief outline
16 that you intend to match --

17 DR. LINGEMAN: Yes, as nearly as we can, but people
18 move around a lot. Some of the materials we get come from armed
19 service bases all over the world. These are not where the
20 people lived or grew up, so you've got a lot of confounding
21 factors in there. We are going to try to match them closely
22 by age, sex, race, where we can. Nowadays, the hospitals are
23 not asking race routinely. We need to know the race because there
24 are differences in cancer rates. For example, cancer of the testes is
25 rare in black men for reasons we don't understand.

1 Hodgkins Disease does not occur as frequently in black men as in white men.

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5 We will try to match them by those factors that
6 we can control.

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8 MR. DeYOUNG: I have a concern about using the AFIP
9 itself as a source of control, and the reason I have that
10 concern -- I may be all wet -- I don't know -- is because the
11 limited information that we have been able to turn up from
12 the military shows that 2,4-D at least and some 2,4,5-T was
13 used quite extensively on military bases as a routine grounds
14 management tool, and as such, I'm not certain that this would
15 enable anyone that is involved with the Armed Forces to be used
16 as a non-exposed control. Now, I am not sure that is critical
17 with this particular study, but I think it needs to be looked
18 at. Possibly we need some more information from DOD on just
19 how extensive these things were, even in a non-tactical appli-
20 cation when, for example, Chanute Air Force Base in central
21 Illinois where I am from has extensive records on 2,4-D in the
22 early '60's.

23 However, the records on 2,4,5,-T have just disap-
24 peared so we have no proof one way or the other on that. This
25 is up through '72 they used 2,4-D. Through '71 they have

1 records on it, going all the way back into the '60's. I can
2 only assume the same was true with 2,4,5-T and if this was,
3 will this scotch the control group for it?

4 DR. LINGEMAN: Well, most of the AFIP accessions
5 are from civilian sources, 60-40 now. We
6 can take one civilian and one military for each patient. That
7 is something we have considered.

8 Using the military man for a control may not
9 a good idea because we can't get the geographic factor
10 matched

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13 MR. DeYOUNG: One more piece of meat for your
14 grinder.

15 DR. LINGEMAN: The average civilian has had great
16 exposure How that will ever
17 be resolved I really don't know. This stuff has
18 been around since the 1940's.

19
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21 MR. DeYOUNG: Good luck.

22 DR. SHEPARD: Dr. Hodder is with us now from the
23 Health Services
Uniformed Services University of the / and we are very pleased to
24 have him as a member of our Committee. Did you have a
25 question, Dr. Hodder?

1 COL. HODDER: No, I just wanted to comment just in
2 answer to perhaps your question is I think you are going to
3 really need multiple controls. I don't think you can get
4 away in this type of an accession system which is not a random
5 sample. It is a well-organized system as multiple sources are
6 bias. You are going to need different -- the question of
7 getting a control group very much different from the cases
8 then you are not going to be able to speak to what caused the
9 difference. So if you will take a control group that was
10 totally non-exposed to military you wouldn't -- there is a
11 considerable selection by -- it is just in the military popula-
12 tion of its own.

13 It is a different population because you exclude
14 people with underlying conditions that may effect disease
15 outcome. On the other hand, you do have to control somewhat
16 for the base that your are looking at, so you would probably
17 have to use a military control group, the random sample group
18 or the 10 percent sample. I think to adequately compare that
19 you have to look at these two groups, two or three control
20 groups.

21 DR. GROSS: One more comment. Dr. Lingeman, isn't
22 it true that the vast -- I am acquainted with things that come
23 to the AFIP, other registries -- isn't it true that the cases that
24 tend to be accessions sent to you by civilian pathologists
25 or military are really non-routine type things? They present

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1 some sort of difficulty where they would like consultations,
2 so their routine garden variety cases really do not get
3 sent to the AFIP;

4 DR. LINGEMAN: That's true. It depends on the
5 pathologist. Some pathologists in a big medical center who
6 have consultants right within their own group are less
7 likely to send them in than the pathologist who is practicing
8 in a small hospital out in Nebraska somewhere who doesn't have
9 access to expert opinions.

10 DR. GROSS: But the clear-cut case is less likely
11 to be sent to you than one with problems?

12 DR. LINGEMAN: Right. The AFIP is more likely to
13 get the difficult ones. On the other hand, this may work to
14 our advantage because we have the greatest difficulties in epidemiologic
15 studies of common /cancers. In other words, if the Vietnam veterans have a
16 lot of lung cancers we have to get a smoking history
17 to correct this and for many^{other} things. The unusual
18 can sometimes give us more information about a common environmental exposure.

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25 DR. SHEPARD: Fine. I think we should take a few

1 minutes break before we get to Dr. Gaffey, so if we could
2 reconvene about 20 minutes after the hour.

3 (Whereupon, a short recess was taken.)

4 DR. SHEPARD: We will resume our deliberations.
5 If you can please take your seats, ladies and gentlemen.

6 Next on our program is a presentation by Dr. William
7 Gaffey who is with the Department of Medicine and Environmental
8 Health in the Monsanto Company in St. Louis. He will give
9 us some, I think, new information on some of the studies that
10 they have been conducting relating to the Nitro, West Virginia
11 episode. Dr. Gaffey.

12 DR. GAFFEY: Thank you very much. My time is limited
13 so I will talk fast and leave off the pearls, but perhaps a
14 little background is appropriate first.

15 The Monsanto plant at Nitro, West Virginia, is a
16 mixed chemical plant, and from about 1948 to 1969 it manu-
17 factured 2,4,5-T. This was, of course, contaminant with
18 dioxins, and we can't now reconstruct with any precision the
19 amount of that contamination, but we are sure it was there
20 because we have had scattered cases of chloracne during the
21 period that the manufacture took place.

22 We have recently, starting about two years ago, begun
23 a series of studies of the plant, particularly the workers
24 exposed to 2,4,5-T. These have typically been cohort studies
25 of mortality in which we identified populations that were

1 exposed in the past, including both those who left employment,
2 those who stayed, those who retired. We followed them,
3 determined whether or not they had died. If so, gotten the
4 cause of death and calculated on the basis of our observations
5 how many deaths we would expect from different causes assuming
6 -- on the basis of the U.S. male population.

7 So these studies have generated observed deaths by
8 cause which we have compared with expected deaths. One such
9 study has been published. It was a study of 121 men who were
10 -- all of whom got chloracne as a result of exposure during
11 an explosion in the manufacturing process in 1949. No excess
12 mortality was found in that group. However, it was small.
13 There were only a total of I believe about 30 deaths.

14 What we have tried to do is to do a study of a larger
15 group of people employed over time in that unit. This is a
16 preliminary report, and you will see the sense in which it is
17 preliminary as I go on. I welcome suggestions about the
18 kinds of analyses we might do further.

19 Now, what we had hoped to do in this study was
20 something very straightforward. We hope to identify everybody
21 who had ever worked at the Nitro plant from World War II up
22 until about the end of 1977, follow them all, calculate their
23 mortality, then divide them up into those who were exposed and
24 those who were not, and have two straightforward studies.

25 Well, we are going to do that, but we have two

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1 difficulties. One is that it is extraordinarily difficult to
2 find out whether a man was exposed. A man has a work history
3 with a couple of hundred jobs in it. If one of those jobs has
4 the right department designations, he was exposed. So finding
5 the exposed people is something like trying to find everyone
6 in the telephone book whose middle name begins with J. They
7 are all there and they can be found, but it is a tedious job
8 and we are doing it.

9 What we managed to do in this case in fact was to
10 identify every person who had worked for at least one year as
11 an hourly worker at Monsanto anytime between 1955
12 and 1977. Before 1955 records on people who left were incom-
13 plete, so we simply had to make that starting date, 1955.

14 We followed these people. There were 885 of them.
15 We managed to find all of them. Of those there were 164 deaths.
16 What we did was to use this information to calculate observed
17 and expected deaths in the whole population. Then our best
18 look at exposure at this instant was done in the following way.

19 We took the people who had died, 164 of them, and for
20 those made a classification of exposed versus unexposed, and
21 then within the exposed deaths and within the unexposed deaths
22 we compared the distribution of causes with the distribution
23 that we would have expected in a typical U.S. male group of
24 U.S. male deaths that were matched for age and year of death.

25 So, in other words, what we have here is what might

1 charitably be called a hybrid. Part of it is a regular cohort
2 study of the whole plant, and then within those who have died
3 we have looked at the distribution of causes of death in those
4 who were exposed compared with those who were not in order to
5 see whether there are, in fact, any differences. Are there a
6 greater percentage of deaths due to cancers in the exposed
7 versus the unexposed?

8 So, very quickly, let me show you some background
9 information on the group that we studied. Oh, let me stop for
10 a moment. Dr. Lingeman mentioned that the calculations
11 involved here are a little bit complicated, and what we have
12 done is use the standard program which was developed at
13 Harvard and is generally available for these kinds of studies.

14 Let's look a little bit at the kinds of people we
15 studied. May I have the first slide, please?

16 I must apologize for these. They were made from a
17 draft and probably are not large -- as large as they ought to
18 be, and later you will see an example of how a table should
19 not be made.

20 (TABLE 1)

21 But at the moment, this is age distribution, and you
22 can see that these people were hired, the bulk of them, age
23 20 to 29, so the median age at hire is in the 20's. So we are
24 looking at a group of people who, when they came to work, were
25 in their mid-20's. Next slide, please.

1 (TABLE 2)

2 When did they get hired? Well, again, the median
3 hire date is somewhere around 1940, so, again, roughly
4 speaking, the population was in their mid-20's when they were
5 hired, and they were hired sometime in the '40's, the typical
6 person. Next slide, please.

7 (TABLE 3)

8 How long did they work? Well, this is not in 2,4,5-T.
9 This is their total duration of employment at Monsanto, and
10 you find it's kind of uniformly spread. About a quarter of
11 them were short-termers, less than 10 years, and a quarter
12 each in the 10 to 20, 20 to 30, and 30 ^{years} plus. But it is inter-
13 esting, and of the group approximately half of them worked
14 more than 20 years which means that we had for about half of
15 them we had more than a 20-year latency period.

16 (TABLE 4)

17 Let's look at the next slide. This is an example
18 of how not to make a slide. I'm sorry. There is too much
19 information on it, but perhaps I can point out the things that
20 are of interest.

21 What we've done is use causes of death as they are
22 classified in standard Government publications of mortality by
23 cause. The death certificates that we got as part of the study
24 were coded by a state health department so that the determina-
25 tion of the cause of death was done as part of that department's

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1 routine on the same basis as the determinations underlying
2 the national statistics.

3 Don't worry about these too much. These are just
4 the code designations in the WHO classification system for
5 causes of death. We observed a total of 163 deaths. We would
6 have expected 158 based on U.S. national figures. That says
7 that the overall mortality is 3 percent more than expected.
8 I will have more to say about this later.

9 If you look down -- I've got observed and expected
10 deaths and I have a column here that says SMR. That is the
11 ratio of the two of them expressed as a percentage, so if this
12 value is over 100, it means that the observed deaths were in
13 excess of what one would expect. This is corrected for age
14 and for date of birth.

15 The things that strike you -- some of these things
16 are not important, like all malignant neoplasms from the 13
17 percent excess -- that is not important. What is important
18 is the specific site which contributes to that excess, and if
19 we look down here, essentially what we find is respiratory and
20 a rather spectacular increase from bladder cancer and some
21 increase in arteriosclerotic heart disease.

22 Well, also external causes of death; accidents,
23 violence, homicide, suicide. Perhaps we had better dispose
24 of this one first. Here we have a mortality from bladder
25 cancer that is nine times as high as expected. Yes?

1 DR. GROSS: Just a question of clarification. When
2 you talk about cause of death did you -- what exactly is that?
3 Is that a primary or a single cause of death or it indicates
4 that -- suppose they were multiple diagnosis. Suppose somebody
5 died of pneumonia, but he happened to have had bladder cancer.
6 How would this be counted in your table?

7 DR. GAFFEY: We have used the underlying cause of
8 death.

9 DR. GROSS: A single one for a --

10 DR. GAFFEY: A single one. The ground rules for
11 determining that cause of death are essentially the WHO regu-
12 lations except that we sent the certificates
13 to a coder in the state health department who routinely codes
14 that. In the example you gave, if the man had died
15 of pneumonia and had been suffering from bladder cancer at the
16 time, the cause of death would have been pneumonia, if the
17 doctor filled out the certificate correctly, because the
18 primary dependence on the certificate is on the judgement of
19 the doctor. If he puts the -- The certificate says, "This man
20 died from A due to B due to C," and if in the physician's
21 opinion, the cause of death really was bladder cancer, he would
22 have put, "This man died of pneumonia, the immediate cause, due
23 to bladder cancer." If he had so noted we would have said
24 bladder cancer.

25 There are difficulties with cause of death on death

1 certificates.

2 DR. GROSS: Yes.

3 DR. GAFFEY: And the only thing that can be said
4 for them is that we have no alternative. You see, these are
5 people, most of whom we get the files of the Social Security
6 system. We have no way of reaching them. We can find out if
7 they died and we can get their death certificates because
8 those are generally public documents, but for better or worse,
9 we are stuck with the death certificate diagnosis, and so if
10 we were able to get information on pathology, for example, our
11 certification would be much more correct, but it would then
12 not be comparable with the national statistics.

13 Our problem is to preserve the proper degree of
14 mediocrity in determining cause of death, so that we can be
15 comparable to the public figures.

16 This excess here comes from an entirely different
17 cause. One of the things manufactured at Nitro is something
18 called paramenobithenol, PAB, which is a bladder carcinogen.
19 Manufacture of that ceased in 1954 I believe or '55, but the
20 people who were exposed to it were placed on a roster and
21 followed and examined regularly because the exposure was known
22 to have placed them at a risk of bladder cancer, so of the
23 9 bladder cancers here, 7 of them were on that follow-up
24 roster and had been exposed to PAB, so I think that fairly
25 well accounts for that.

1 The others? Well, let's look at the next table and
2 we can get a little more detail on some of these things.

3 (TABLE 7)

4 This one you're really going to need a microscope
5 for. I must again apologize. We looked at this information
6 by year of hire on the theory that the earlier the hired date
7 the longer the latency, and, of course, as you would expect,
8 those hired after 1960 are remarkable healthy, didn't have any
9 time to die.

10 Some of these other things are -- we see about the
11 same pattern of excess. We've got excess respiratory cancer
12 roughly the same in these two periods. We've got the excess
13 bladder cancer, again as I recall all of the 7 PAB bladder
14 cancers were in this date, so when you take those out, we
15 don't -- there's not going to be much going on.

16 Again, although I don't have it in the table, if
17 you were to look at the observed expected ratio for arterio-
18 sclerotic heart disease, it also is high here, here, and it's
19 gone from here. Next slide, please.

20 (TABLE 8)

21 Now, I want to talk about among the deaths the
22 division of these people into whether or not they were exposed
23 to 2,4,5-T. Now, exposure here means that they worked in the
24 unit from which the material was manufactured. We don't have
25 any air sampling measurements or anything of that kind that

1 gives an objective evidence of exposure, but we presume anybody
2 who worked in the unit had at least an awful lot more exposure
3 than anyone in the general population would have had.

4 It turned out that of the 163 deaths, 58 had been
5 exposed, 104 had been non-exposed, and 1 we didn't know, so
6 that 1 is missing from our substantive analysis. Next table,
7 please.

8 (TABLE 9)

9 This is the one that is interesting.

10 DR. GROSS: Excuse me. Back to the previous slide,
11 how would this compare with the population during that time?
12 I mean this is -- well, what is the ratio of exposed to non-
13 exposed in general?

14 DR. GAFFEY: I don't know which is one of the
15 reasons that this is a preliminary study. That is -- see,
16 this --

17 DR. GROSS: Again, to exaggerate here, suppose
18 that you had four or five times non-exposed people during
19 that time to expose. This would be very significant, would
20 it not?

21 DR. GAFFEY: Yes, it would.

22 DR. GROSS: I see.

23 DR. GAFFEY: Yes, it would, and what we are in the
24 process of doing is making that determination so that we can
25 indeed say that. Next slide, please.

1 (TABLE 9 still being shown)

2 Yes, the difficulty here is that what I am going to
3 show you now is how -- here we have -- I have looked here in
4 the exposed and unexposed only at malignant neoplasms because
5 they seem to be the causes of interest. No, I'm sorry, I'm
6 sorry, that is not true. I've got the rest of it down here.
7 Yeah, I've got the whole thing here.

8 What I have done, however, is I've said, "All right,
9 given that we have a group of deaths, here are the numbers of
10 these deaths in each cause. Here is the number in each cause
11 that you would expect from 58 deaths in a matched deaths from
12 the U.S. male population."

13 So I can look at this distribution, but it doesn't
14 really tell me here whether 58 deaths is too many which is
15 the point that you were making.

16 DR. GROSS: Right.

17 DR. GAFFEY: That is one of the things that remains
18 to be unscrambled here, but for what it's worth, if we look
19 at the cause distribution we see that the proportion of
20 deaths due to cancer in the exposed group is slightly less
21 than you would expect, in the non-exposed group slightly more.

22 Some of the same things turn up here that we saw in
23 the overall plant. We have an excess of lung cancers. Now
24 that occurs in both groups. It looks here as if 168 is a lot
25 bigger than 125, but that's if there were one case less or one

1 case had been misclassified, that would be reverse so it's not
2 terribly overwhelming.

3 A rather monumental excess from bladder cancers
4 again. That, again, is the PAB group shown here. Some excess
5 in diseases of the circulatory system, again heart, but the
6 crucial thing is that the excesses that one sees and the
7 deficits are pretty much matched in the exposed and unexposed
8 group, so if you were to look at these -- this distribution
9 and this one, what you would find yourself saying, I think,
10 is that there doesn't appear to be any difference to speak of
11 between these two groups, but putting them all together we
12 would be a little bit worried about lung cancer and heart
13 disease, irrespective of the exposure to the 2,4,5-T, but
14 just as a study of this plant.

15 Now I will leave that up there for a while because
16 this is really the point of the whole exercise, and you may
17 want to look at it and ask questions about it. Yes?

18 MR. EWELL: My name is Michael Ewell. Doctor,
19 during what -- I have two questions for you. During what
20 period did Monsanto manufacture 2,4,5-T?

21 DR. GAFFEY: I think it started in 1948 and I know
22 it ended in 1969.

23 MR. EWELL: In '69?

24 DR. GAFFEY: Yes.

25 MR. EWELL: Let me preface my other question by a

1 brief comment. It recently came to light that Dow Chemical
2 informed the Government, the Defense Department, of the
3 existence of Dioxin in 2,4,5-T in 1962 saying that it was
4 believed to be a potential health hazard at that time, and,
5 according to Dr. Robert Bachman of Harvard Medical School in
6 his Ph.D. thesis which was published as an appendix in Thomas
7 Whiteside's book, "The Pendulum and the Toxic Cloud," Dow
8 sent a letter to Monsanto and other manufacturers of 2,4,5-T
9 in 1964 alerting them also to the fact that Dow was beginning
10 to experience among its work force certain health problems
11 that they attributed potentially to Dioxin.

12 The question was, what was Monsanto's reaction to
13 that letter in 1964? How did that affect Monsanto's policy?

14 DR. GAFFEY: I am afraid I don't know. I've worked
15 with Monsanto for less than a year and a half, so this is --
16 I'm not aware of the events that you're talking about.

17 MR. EWELL: Who could answer that question at
18 Monsanto?

19 DR. GAFFEY: My first thought is our public informa-
20 tion people. There is a Mr. Daniel Bishop whose telephone
21 number I don't have, but Monsanto's -- well, I can give you
22 my card and you can call me and I can tell you how to reach
23 him.

24 MR. EWELL: Okay. Thanks a lot.

25 DR. GAFFEY: You're welcome. One more comment about

1 this while we're waiting for questions. Among the defects of
2 the study the obvious one is that we haven't yet characterized
3 the exposure of the people who are alive. The other problem
4 is that we compared this mortality experience to that of the
5 U.S. male population. In other words, we haven't taken account
6 of regional differences. We are acquiring the capability to
7 do that, but we don't now have it.

8 But it does turn out that in the -- West Virginia
9 has a higher mortality both from lung cancer and from cardio-
10 vascular disease than the rest of the state -- rest of the
11 states -- and the Kanawa Valley in which the plant is located
12 has a higher mortality from heart disease and lung cancer than
13 West Virginia does, so there is some question as to the
14 extent to which these excesses may ^{be} due to our using a national
15 standard rather than a state or a county standard. Yes.

16 COL. HODDER: Well, that was one of the things that
17 concerned me. Actually if we compare an occupational cohort
18 against the national cohort --

19 DR. GAFFEY: Yeah, sure.

20 COL. HODDER: -- we would expect lower than the 100 --
21 your SMR should be lower.

22 DR. GAFFEY: Yes, for everything except cancers and
23 certainly, particularly cardiovascular disease, it ought to
24 be lower, but as I say, what I think -- so there is no doubt
25 that part of this excess is due to the fact that we're using

1 a national standard when perhaps we should be using a state or
2 more local standard.

3 DR. GROSS: A cohort of people employed in these
4 kind of jobs is the important point because their standard of
5 health would be different than the general population..

6 DR. GAFFEY: Yes, and to the extent that we study
7 occupational cancers this is not too serious a problem because
8 the evidence seems to be that the healthy worker effect
9 doesn't extend much to cancer. As soon as we get into cardio-
10 vascular disease we are in trouble. We are in trouble, and
11 so I don't really know -- I would still like to see how this
12 compares with the local rates because if that excess disap-
13 pears, I would feel comfortable. If it didn't, I would say,
14 "Well, we're going to see what -- do something like a case
15 control study to unscramble more carefully the exposures,"
16 because the other thing we have done here, of course, is
17 we have ignored all other exposures at the plant.

18 For the purposes of this particular study we have
19 concentrated on 2,4,5-T and said everybody either is or is
20 not and have taken no account of the other things that he was
21 exposed to.

22 MR. DeYOUNG: Well, you said earlier that when a
23 person is simply working in a particular unit where T was
24 handled constituted exposure. Is the other side of the coin
25 as open-ended? In other words, does non-exposure simply mean

1 that they did not work in proximate contact with the material?

2 DR. GAFFEY: Yes.

3 MR. DeYOUNG: So it's not that they were wearing
4 special suits or something of that nature?

5 DR. GAFFEY: Oh, no, it meant that they did not work
6 in the area in which the material was produced.

7 MR. DeYOUNG: Well, this is --

8 DR. GAFFEY: So our definition of exposure is
9 geographic location with respect to the unit that produced it.

10 MR. DeYOUNG: I appreciate the difficulties. We're
11 having the same trouble with the Vietnam troops.

12 DR. GAFFEY: Uh huh, yes.

13 MR. DeYOUNG: It's simply being there.

14 DR. GAFFEY: We did try one more thing. We are
15 trying to get a roster of everybody who got -- who made a
16 medical claim for chloracne which is another way of charac-
17 terizing exposure. We are having difficulty because the
18 degree of specificity of medical claims, particularly 10 or 15
19 years ago, is not that great. Dermatitis, was it or wasn't it?

20 Our policy so far has been to say, "Well, when in
21 doubt, call it chloracne," but that may be the wrong thing
22 to do. We may be diluting our chloracne group with people
23 on other dermatitis. Anyhow, we're trying to assemble a
24 roster. What we will do with it I am not quite sure. It
25 presents a problem.

1 DR. SHEPARD: Thank you. I have a couple questions
2 from a Melena Barkman. Is she here? Okay. I'll read your
3 question if that is all right with you.

4 First question: Why does the study group not
5 include persons employed between 1948 and '55?

6 DR. GAFFEY: Because those records are a mess. We
7 don't know what happened. Those persons who terminated after
8 '55, records were retained for them. For the period before
9 1955 we can tell by looking at Social Security quarterly
10 returns that there were people in the plant whose records are
11 not there, who terminated and whose records were in some way
12 or another destroyed.

13 The records that are there are also incomplete. We
14 have done some straightening out of them, but there is enough
15 missing data on terminations that we would bias the study if
16 we tried to take the people that we knew about. So
17 we for these reasons stopped at '55 because it was rather a
18 sharp dividing point in the plant records. Terminations after
19 '55 are stored in a different place and are relatively
20 complete. Terminations before '55 are stored in another
21 location and are not complete. It's just a fact of the
22 archives of the plant.

23 MS. BARKMAN: I was just wondering if Dr. Suskind's
24 morbidity study wouldn't help you to find the people that were
25 exposed in the spill of 1949.

1 DR. GAFFEY: No. You see we gave him that informa-
2 tion, and that was based -- and we do not know who was
3 exposed in the 1949 spill. All we know is who was exposed
4 and got chloracne, because we identified that group by looking
5 at medical treatments right after the incident. These people
6 got chloracne and they got kind of sick otherwise, so there
7 were presumably more people involved in the explosion and the
8 cleanup who did not get chloracne and, therefore, never came
9 to medical attention and we don't know who they were.

10 MS. BARKMAN: And there were no company documents
11 or records that supplied --

12 DR. GAFFEY: No, because these were not people who
13 worked in the unit. See, the unit blew up over a weekend,
14 and the 120 that we are talking about were people from other
15 units who were called in to clean up, so nowhere in their
16 record does it say that they worked in the 2,4,5-T unit.

17 And so presumably other people who were involved in
18 the cleanup and who did not get chloracne are sitting out
19 there with the exposures, but we have no -- in the absence,
20 since there is no medical record because they didn't get
21 chloracne, there is no work history record because they weren't
22 assigned to that unit. We have no way of knowing who they are.

23 MS. BARKMAN: And there is no report at the spill
24 that names these people?

25 DR. GAFFEY: No. I haven't seen any. I've seen

1 reports that named the chloracne cases and people who presented
2 themselves as being sick. I am aware of no document that
3 names the people who -- that names people other than those
4 who got chloracne.

5 MS. BARKMAN: And you did not include the chloracne
6 named individuals in the study?

7 DR. GAFFEY: If they were still working in 1955 they
8 were in the study. I can't tell you off hand how many of them
9 were. I suspect most of them were in here.

10 MS. BARKMAN: That goes to my next question I think.

11 DR. SHEPARD: Okay. How many of the 58 decedents
12 were working during the 1949 spill?

13 DR. GAFFEY: I don't know at this moment. My guess
14 is that almost all of them were. That is, in the original --
15 in the group in the original spill we found 30 deaths. The
16 only way one of those deaths could be missing from this study
17 would be if the man had quit before 1955, and I don't think
18 that happened. That is information that is easy to find. I
19 just don't happen to have it at my fingertips.

20 DR. SHEPARD: And the third question, what is the
21 95 percent confidence interval around your estimate of risk
22 for liver cancer and all cancer?

23 DR. GAFFEY: I don't have the confidence interval,
24 but I could tell you that it includes 100 because the liver
25 cancer -- we had no deaths from liver cancer which I guess is

1 significantly low, but not all that low. We would have
2 expected six-tenths of a death and we got zero. I'm
3 afraid I don't know what the confidence interval is.

4 For all cancer I haven't calculated it, but since
5 I know it's statistically significant, I know the confidence
6 interval includes 100.

7 DR. GROSS: Dr. Gaffey, do you believe that
8 Monsanto would be willing to encourage the people or the
9 estates of the people that died and morphologic material
10 exists to make this material available to Dr. Lingeman's
11 Registry, particularly in the case where people had known
12 exposure to that or studied it?

13 DR. GAFFEY: I am convinced that my boss who is
14 the Medical Director of Monsanto would be strongly in
15 favor of that. What we can actually do I don't know, but
16 as far as taking a position on that, I am in a
17 sense in the classical bureaucratic position. I haven't
18 cleared it with my boss, but I know that -- I feel confident
19 that he would be certainly anxious to assist in this.

20 DR. SHEPARD: The following question, then, do
21 you have any information as to how many of these were
22 autopsied?

23 DR. GAFFEY: No, I don't because theoretically on
24 a death certificate there is a place that says "Autopsy,"
25 and says, "Yes/No," and the most common thing you find is

1 that neither of them is checked. And more than that, many
2 autopsies are performed after the death certificate is
3 filed, so the certificate goes in with no autopsy.
4 Theoretically, if the autopsy changes the cause of death,
5 there should be an amended certificate filed, but if it
6 doesn't change the cause of death, it won't be filed, and
7 so even when you see a notation of no autopsy, there may
8 in some cases be^{an} autopsy.

9 So we didn't try to make this distinction because
10 it wouldn't have helped us as far as our comparison with
11 population figures in which this distinction is usually
12 not made.

13 DR. SHEPARD: Dr. Lingeman?

14 DR. LINGEMAN:

15 If on ^{the} death certificates a diagnosis of cancer is made or
16 if it is even worse, if the particular kind of cancer
17 is named, but there very likely wasn't a biopsy --
18 how many hospitals are there in Charleston?

19 In Louisville
20 around the time of the vinyl chloride thing, there were
21 about eight hospitals involved. A man from CDC
22 went around to each one of the hospitals with the names
23 -- and said, "Do you have any tissue on this man or that
24 man?" And so it is possible to get those kind of material
25 although the hospitals may not save material after --

1 a certain time. They will save their slides up to --
2 so this material is very difficult to get really. You can
3 come up with about a 50 percent retrieval rate, but it is
4 possible. It just takes a lot of work to go from the
5 death certificate to the physician who signed, ask him
6 where the operation was done.

7 Sometimes the death certificate will contain the
8 information that the patient died in a certain hospital
9 where it's easier if it's diagnosed there.

10 DR. GAFFEY: It is a little more difficult than
11 that because in many states we can't get a certificate
12 without promising we won't contact anybody named on a
13 certificate.

14 DR. LINGEMAN: How about West Virginia? Is it --

15 DR. GAFFEY: I don't recall. That is not an
16 insurmountable obstacle because you can always go back to
17 the vital register and explain what you are doing and very
18 likely he will say, "All right," you know.

19 DR. GROSS: Dr. Shepard, I would like to make a
20 motion that this Committee express a desire to the Monsanto
21 Company to help facilitate making this material available
22 to Dr. Lingeman's registry if possible.

23 DR. SHEPARD: Fine. I think that is a very
24 appropriate suggestion. If it is all right with you, I
25 will take it upon myself to draft a letter to the Medical

1 Director of Monsanto and request that they make the records
2 available in such a fashion that a follow-up effort might
3 be entertained in trying to retrieve the tissue material.

4 MR. DeYOUNG: Excuse me, Dr. Shepard. One final
Start 2B 5 question for Dr. Gaffey. I noticed that you mentioned that
6 external causes of death were up in this population. Has
7 there been any workup whatsoever on that category more
8 intensive than simply saying it's up?

9 DR. GAFFEY: No, we haven't.

10 MR. DeYOUNG: Would that data be available for
11 study?

12 DR. GAFFEY: Well, we have the individual death
13 certificates with the causes of death, so we would know
14 whether it was homicide or an automobile accident or what
15 have you. I frankly suspect that one of the causes in
16 which the excess would disappear if we used the rates for
17 that state.

18 MR. DeYOUNG: Do you suspect that external causes
19 are outdated in West Virginia?

20 DR. GAFFEY: Yes, that accidents, homicide are
21 higher than the national average.

22 MR. DeYOUNG: I for one would be interested to
23 see a categorical breakdown similar to this for simply that
24 category. It has been our experience with the veterans
25 involved that -- or -- let me back up -- if the allegations

1 from veterans are correct and they seem to me to be, there
2 are some personality changes in aggression and things like
3 that which may go into making up an excess of violent
4 death, and I for one would like to see the statistics on
5 what kinds of external causes were involved.

6 DR. GAFFEY: I am writing myself a note to send
7 you a listing with no names, but with the cause as written
8 on the certificate and probably the age of death, something
9 like that, so perhaps later I can get an address to which
10 I can send this.

11 MR. DeYOUNG: By all means.

12 DR. SHEPARD: Maybe, Dr. Gaffey, if you could
13 send that to me and then I will distribute that information
14 to the members of the Committee.

15 DR. GAFFEY: Fine.

16 DR. SHEPARD: Yes, Cheryl?

17 MS. BEVERSDORF: Has this ever been published?

18 DR. GAFFEY: No, it has not because we are con-
19 cerned about the issue that Dr. Gross raised, that as it
20 now stands we don't know how many living people were
21 exposed, and I don't propose to publish it until we have a
22 more complete characterization of the exposure status of
23 the people who are alive. I am perfectly prepared to talk
24 about it. There is nothing confidential about it. It's
25 just that publication means subject to a period of review

1 and so on, and it's desirable to publish, but I don't think
2 the study is clean enough as it stands to really justify
3 publication.

4 MS. BEVERSDORF : Do you have any idea when --

5 DR. GAFFEY: I would guess in a couple of months
6 because the unscrambling that I'm talking about is now
7 going on.

8 DR. SHEPARD: Thank you very much, Dr. Gaffey,
9 for that fine report, and we will be looking forward
10 anxiously to the final public report. We really appreciate
11 your taking your time to come.

12 DR. GAFFEY: Thank you.

13 DR. SHEPARD: We are running a little bit behind
14 our agenda, however. I think we are doing reasonably well.
15 Next I would like to call on Mr. Charles Thompson who I
16 hope will be able to say something about the Senate
17 Veterans Affairs' Committee questionnaire. Maybe, Charlie,
18 if you could just give a little bit of background as to
19 how that came about and then your understanding of where it
20 stands now.

21 MR. THOMPSON: Yes, I certainly will. Thank you,
22 Dr. Shepard.

23 First, I am certainly glad that we have reached
24 a happy medium with the air conditioning and heating system
25 in this building.

1 Just for an historical outlook on the question-
2 naire itself, approximately June of 1980 we were contacted
3 along with other major veterans' organizations from the
4 Senate staff asking us if we would be interested in dissemi-
5 nating a questionnaire, non-scientific, out to our field
6 representatives concerning VA examinations on Agent Orange.

7 We had a chance to meet with the staff, go over
8 the questionnaire, delete and amend. We finally had it all
9 together and we sent out approximately 4,000 questionnaires.
10 The DAV sent out approximately 1,500 to 2,000 of these
11 questionnaires.

12 There was some concern with regard to not only
13 the type of examination that was being given, also counsel-
14 ing. There was some regard to the physicians' thinking on
15 Agent Orange, not all that conducive. They expressed the
16 thought that many of these veterans did not have legitimate
17 claims. We were certainly concerned with this.

18 Also we were concerned with the follow-up that
19 was given Vietnam veterans and the counseling. There was
20 none. They were given blood tests, various other kind of
21 testing, and the veteran was never contacted again. We
22 were certainly concerned about this.

23 As of this date, and I thought I was going to
24 have some backup here, Molly Milligan from the staff was
25 going to be here to give you a current assessment of the

1 questionnaire. However, I have been informed that she was
2 a little ill. I am not sure if that has to do with the
3 elections or not, but --

4 DR. SHEPARD: She was here a little while ago.
5 I saw her, didn't you, Cheryl?

6 MR. THOMPSON: She had a chance to give me a
7 current tabulation of the questionnaire, the questionnaire
8 itself, and a state-by-state breakdown of who has responded.
9 and I have copies here for everybody on the Committee. I
10 don't think I really need to delve into it because really
11 out of those 4,000 responses only 124 have been returned
12 so far, so it is still a tad bit early to reach any con-
13 clusions on it.

14 DR. SHEPARD: I understand you -- only 120 have
15 been returned of the total that your organization sent out?

16 MR. THOMPSON: Approximately 124. This is all
17 totaled out of the 4,000 that were sent out. This was by
18 the DAV, the VFW, and the AMVETS, and of course the Ameri-
19 can Legion had their own questionnaire made up and sent
20 out.

21 DR. SHEPARD: Okay. Thank you very much. I
22 might just point out that we are very interested obviously
23 in this questionnaire and the one that the American Legion
24 is working on, and we certainly will make good use of this
25 information and use it as a method, hopefully, for improving

1 the whole process.

2 We have conducted also a very small sample, a
3 satisfaction questionnaire. We have approximately a 50 per-
4 cent return and we will be sharing that information with
5 the Committee also.

6 MR. THOMPSON: One other thing, Dr. Shepard.
7 Mollie Milligan did indicate to me that this Committee
8 would be kept abreast when a conclusion is reached or when
9 further documentation comes in, and you will be provided
10 with copies then.

11 DR. SHEPARD: Yes?

12 MR. ENSIGN: I'm struck -- that seems like a
13 very low response rate. Just to be clear, the 4,000 were
14 sent to Vietnam veterans in your organization who had
15 made an Agent Orange claim or was it just sent generally
16 to your membership?

17 MR. THOMPSON: Okay, first of all, it was not
18 sent to the membership. It was sent to our National
19 Service Officers in the field that deal directly with the
20 veteran population. The DAV, speaking for the DAV, we
21 have offices at every VA Regional Office throughout the
22 country. Our people, when an individual goes in for an
23 examination, our people counsel with them and when, in
24 fact, a Vietnam veteran would come in, we would give him
25 this questionnaire, and he would, in turn, fill it out or

1 supposedly try to fill it out and send it back directly to
2 the Senate Committee on Veterans Affairs.

3 I can't speak for exactly how the AMVETS or the
4 VFW disseminated the questionnaire, but that is how we
5 did it.

6 MR. ENSIGN: How long ago did you mail yours?

7 MR. THOMPSON: Well, that was -- that's only
8 been a few months ago.

9 DR. SHEPARD: Thank you, Charlie. Any other
10 questions?

11 SPEAKER: Could we have it passed around now?

12 DR. SHEPARD: Yeah, that would be fine.

13 Okay, why don't we ask Ron to tell us a little
14 bit about his view of the videotape which we will be
15 seeing shortly, and we will get comments afterwards as
16 well, I am sure?

17 MR. DeYOUNG: I would hope so. I hate to do
18 these things in a vacuum.

19 The videotape that Dr. Shepard is referring to
20 was tentatively titled "Agent Orange: A Time for Reason."
21 It was produced, as you heard earlier, by the St. Louis
22 Regional Medical Education Center of the VA, and it was
23 set up for three major purposes.

24 In a concept team meeting, oh, possibly eight
25 months ago at this point, we identified three major

1 purposes that we wanted to serve with such a videotape, and
2 those were to give basic scientific and military informa-
3 tion about Agent Orange and the other herbicides to veter-
4 ans, to begin to fill some of this ignorance gap that we
5 had since this broke over two years.

6 The second point was to allay unnecessary fears
7 among the veterans population, specifically in the area of
8 birth defects, cancer, and the extremely traumatic inci-
9 dences, and that to put some perspective on the
10 fact that a pregnant wife of a Vietnam veteran is not 100
11 percent certain of giving birth to a child that is deformed,
12 and so forth.

13 The last and possibly the most important use of
14 this videotape is to encourage and lay out the guidelines
15 by which a veteran would participate in the VA programs.
16 What we are looking for here is some steps towards a
17 constructive solution of these, although we knew that
18 wouldn't come overnight.

19 Information was gathered from the VA, of course,
20 and from different branches of the VA, from benefits and
21 medicine and surgery and so forth. Much of the basic
22 information that went into the scientific background of
23 the tape is from the Air Force, from Major Al Young whom
24 many of you have met here in the past, along with most of
25 the medical information about symptoms, body systems of

1 interest, and so forth.

2 Information was also from veterans through
3 veterans' organizations, and much of this has gone into the
4 underlying fabric of the tape, although you won't hear any
5 direct quotes.

6 The final element was individual scientists,
7 literature reviews, and so forth which went into this.

8 I am especially interested to see this Committee's
9 reaction to the scientific information that we put in the
10 film -- in the tape. The question that I would ask the
11 Committee and the audience, for that matter, to keep in
12 mind is this thing scientifically accurate? Does it say
13 all we can say about Agent Orange in the layman's terms and
14 still be honest, objective, and obtain these other objec-
15 tives that we started out for?

16 As I would think would happen with any process
17 like this, the final product that we have at this point in
18 no way resembles the original we started with. It is, as
19 Dr. Gaffey said, rather generously a hybrid, and I would
20 expect that ears will perk up to statements depending on
21 your own point of view.

22 That's what I am looking for personally in this.
23 Please respond in the future -- the short future -- with
24 what sets off your alarm bells. That is what we need to
25 know. We need to know where we are going wrong, if

1 anywhere, in this tape.

2 DR. SHEPARD: Again, thank you, Ron. I think
3 that is a nice wrap-up of the process. We have had the
4 opportunity to review this as Layne has said. You will
5 notice that on the tape, and by the way I have not myself
6 seen this latest version although I think it won't be very
7 different from the one we recently saw, it has not been
8 completed yet. There will be some gaps in the video
9 portion of it, I believe, gaps which are still being
10 finalized.

11 Because we are anxious that the public media will
12 make use of this tape, there I think is the opportunity for
13 public service announcements. So there will be breaks from
14 time to time.

15 The question of the name, the title, of the tape
16 has been raised. It was originally suggested to be "Agent
17 Orange: A Time for Reason," which at first blush seems a
18 fairly benign name. However, after some reflection some-
19 body thought that the hidden implication might be that if
20 you don't agree with this tape you are not reasonable, and
21 so we had made a suggested change and the Policy Coordi-
22 nating Committee has made that recommendation that we
23 rename it "Agent Orange: A Search for Answers," which I
24 hope will not offend anybody's sensibilities.

25 Okay, I think that since we are now talking about

1 the tape and that seems to be the current subject, why
2 don't we go ahead and show the tape, although this will be
3 shifting the agenda around a little bit, and then that will
4 naturally flow into an opportunity for comments, not only
5 on the tape but any other questions that members of the
6 Committee or members of the audience may raise.

7 Can you all see it?

8 (At this point the videotape "Agent Orange:
9 A Search for Answers," was played.)

10 THE NARRATOR: During the years of American
11 involvement in Vietnam the United States military personnel
12 fought two on-going battles, one with the enemy troops and
13 the other with the dense jungle that hid the enemy and his
14 movements, provided a screen for ambushes, and in general
15 made an already difficult situation worse.

16 While this human enemy proved to be illusive and
17 often hard to engage, the jungle provided a more obvious
18 target and one that would yield to herbicide technology.
19 The weapons used against this enemy went by many names,
20 orange, white, blue, green, purple, pink, each for a
21 slightly different target vegetation, but the same result,
22 defoliation.

23 Defoliation by herbicide was one of the truly
24 successful campaigns of the war. Unfortunately, exposure
25 to the herbicides was not limited strictly to the vegetation

1 in Vietnam. American troops loaded and executed the
2 spraying missions. American troops patrolled defoliated
3 jungle. Some American troops lived in camps where perime-
4 ters were defoliated to provide a clear field of fire and
5 reduce the likelihood of surprise enemy attacks, and,
6 although similar herbicides had been used for agriculture
7 and forestry in our own country for 15 or 20 years before
8 the Vietnam conflict, the full range of health effects
9 from human exposure are still a matter of scientific and
10 public controversy.

11 And so, the legacy of Vietnam may still be with
12 us. No longer in the headlines of daily body counts or
13 nightly news footage of combat action, but in the names
14 Agent Orange, Dioxin, and in the concerns of Vietnam
15 veterans who fear possible ill health as a result of herbi-
16 cide exposure.

17 This program will not get involved with the con-
18 troversies surrounding the Agent Orange issue. Scientific
19 and medical research will eventually provide those answers.
20 While much is being said on both sides of the issue and new
21 developments are appearing regularly, many questions still
22 remain unanswered. This program will tell you what is
23 known and agreed upon regarding the human effects of herbi-
24 cide exposure. You will see locations of major herbicide
25 spraying missions and the military units that were active

1 in those areas of Vietnam.

2 Most importantly, you will learn what the Veter-
3 ans' Administration is doing about Agent Orange and how you
4 can help yourself and the VA's efforts by cooperating in
5 several VA programs. This will be a low-keyed reasoned
6 approach to your questions surrounding Agent Orange.

7 It is a very emotional issue, we realize. Vet-
8 erans are concerned not only with their own health, but
9 with the health of their families. Some veterans feel a
10 time bomb of herbicide effects lurking within their bodies
11 even though they might not have any symptoms now. There
12 is fear of birth defects, of cancer, of psychological
13 changes.

14 Perhaps the greatest anxiety comes from the fear
15 of the unknown, of what is not known about the effects of
16 herbicide exposure at present. We can suggest few answers,
17 but we ask you to listen to this program and to consider
18 the information presented, and we ask you to take an active
19 role by participating in the Veterans' Administration
20 activities related to Agent Orange.

21 In a moment we will take a brief look at herbi-
22 cides themselves, what they are, why, and how they were
23 used in Vietnam.

24 American farmers and forestry workers have used
25 herbicides since they were developed in the 1940's. They

1 have been used in large quantities around the world on the
2 whole without causing any immediate hazards. Herbicides
3 are chemicals used to kill unwanted plants, weeds, and
4 other types of vegetation.

5 The commonly used herbicides work generally by
6 dehydrating the plant or by depleting its food supply.
7 Although herbicides were not developed specifically for
8 military use, they were used in Vietnam to achieve several
9 tactical objectives, primarily to limit the risk of ambush
10 by depriving the Vietcong of cover and to reveal the
11 staging areas of Vietcong activities.

12 In addition, herbicides were used on crops to
13 deprive the enemy of food. While the majority of herbicides
14 were applied on contested territory, the chemicals were
15 also used to clear some American base and camp perimeters
16 for defense and along supply routes and communication lines.

17 A breakdown of total herbicide use by objective
18 would be roughly 90 percent for forest defoliation, 8 per-
19 cent for crop destruction, and the remaining 2 percent for
20 clearing of base perimeters. Several herbicides were used
21 in Vietnam. They were code named Orange, White, Pink,
22 Green, Purple, Blue. These names did not reflect the
23 actual color the substance, but rather markings on the
24 barrels indicating which herbicide was contained. Of the
25 group, the herbicide Orange accounted for 94 percent of all

1 the herbicides used in Vietnam between 1962 and 1971.

2 Herbicide orange itself is a thick, reddish brown,
3 foul-smelling, 50-50 mixture of two phenoxy herbicides,
4 2,4-D and 2,4,5-T. When 2,4,5-T is manufactured there is
5 an unavoidable byproduct produced, a contaminant known as
6 TCDD or dioxin. In its pure form dioxin is one of the most
7 highly toxic chemicals known to man. It is dioxin that is
8 currently the subject of the closest scientific study and
9 debate.

10 It was present in minute amounts in the herbi-
11 cide Orange sprayed in Vietnam and used in this country.
12 We will discuss dioxin more when we begin to consider
13 possible health effects from herbicide exposure.

14 Herbicides were first brought into Vietnam in
15 1962 and used on a limited basis until 1965. Because of
16 the remarkable success of this technique, the use expanded
17 in 1965 through 1969. The spraying missions using herbi-
18 cide Orange were stopped in 1970.

19 Herbicides were an effective tactical weapon
20 used successfully in support of troop operations. Their
21 use probably saved thousands of lives. Herbicides were
22 disseminated in several ways. Ninety percent of all herbi-
23 cides applied in Vietnam were sprayed by thick-wing air-
24 craft in the Air Force Ranch Hand Operation. The aircraft
25 used were camouflaged C-123's. It is important to note

1 that only between 8 and 10 percent of Vietnam's land mass
2 was sprayed, and, for the most part, in areas where our
3 troops were not located at the time of spraying.

4 Other but lesser used methods of disseminating
5 herbicides were by helicopter and by spray equipment
6 mounted on trucks or boats or by hand-operated backpack
7 units. It should be remembered, though, that by far the
8 greatest amount of herbicide was sprayed by camouflaged
9 C-123's.

10 In addition to herbicides, there were other
11 chemicals used in Vietnam. For example, insecticides were
12 used to control one of the most dreaded and deadly diseases
13 of the war, Malaria, so although you might remember being
14 sprayed or walking through recently sprayed jungle, it
15 doesn't necessarily mean that you came into contact with
16 Agent Orange. It could have been any number of substances.

17 This map indicates areas of major herbicide
18 spraying missions and also the location of the Corps Areas.
19 This is general information and will only give you an indi-
20 cation of the major spray sites. As you can see, the total
21 area sprayed was relatively small. Just because you were
22 in a unit near a heavily sprayed area doesn't mean that you
23 were exposed. Likewise, just because you weren't assigned
24 near a spray zone doesn't rule out the possibility that you
25 might have been exposed.

1 Also, if you were involved in one these key
2 mission areas, there is a chance that you came into contact
3 with herbicides to some degree. Ashaw Valley, DMZ, Rung
4 Sat, south and southeast of Saigon, these were areas of
5 concentrated spraying.

6 Now that you have seen the areas of the heaviest
7 herbicide application in relation to major military units,
8 let's speculate on some of the ways that you might have
9 come into contact with herbicide orange or its counterparts.
10 These are hypothetical possibilities, impossible to docu-
11 ment or prove.

12 They seem to fall into three main categories:
13 direct contact, actually handling the herbicides or being
14 directly sprayed; entering a recently sprayed area; and
15 exposure through food or water. The veterans at greatest
16 risk of exposure are those 1,200 in the Ranch Hand Opera-
17 tion. This operation involved actually handling the herbi-
18 cide, loading the drums for the sprayer, flushing the spray
19 system, riding in the cargo bay with the herbicides.

20 Associated with Ranch Hand Operations are ground
21 support personnel, those who might have drained the residue
22 out of the drums or operated the machinery for moving the
23 drums about, or maintenance crews who might have come into
24 contact with herbicide residue while working on the Ranch
25 Hand aircraft.

1 There are others in other branches of the service
2 who might also have come in direct contact with Agent
3 Orange. Perhaps you loaded herbicides from a drum to a
4 backpack sprayer or even operated the sprayer yourself.
5 Perhaps you were involved with handling the drums, trans-
6 porting them from the dock to a holding or loading area.
7 You might have been a door gunner on one of the helicopters
8 that was also used for spraying herbicides, or you might
9 have actually served on some spraying missions.

10 These are all occupations that are considered to
11 have the highest risk of exposure because of the chance of
12 actual direct contact with the herbicides. We are not
13 suggesting any conclusions about health effects from this
14 exposure. We are only trying to point out the individuals
15 who have the greatest chance of being exposed.

16 Many veterans express concern over whether or not
17 they could have been exposed to Agent Orange by patrolling
18 or walking through treated jungle. You probably would have
19 known if you were in a defoliated area. Brown, dried
20 leaves or no leaves at all, trees dying from the top down.
21 Plants and foliage generally show maximum effect of herbi-
22 cides after a period of a few weeks.

23 However, dioxin begins to photo-degrade or break
24 down in sunlight within a few minutes, so if you remember
25 being in a defoliated area like the one described, chances

1 are that the area had been treated weeks earlier and that
2 much if not all of the dioxin was in the process of
3 breaking down.

4 In addition, the triple canopy of the jungle
5 intercepted most of the spray. Therefore, the amount of
6 herbicide and dioxin actually reaching the jungle floor
7 was probably small. Again, the risk of contamination most
8 likely decreased with time.

9 The likelihood of significant exposure from
10 eating local food is slight. As for crop foods, the
11 appearance and odor would have made them highly undesirable
12 sources of food. The look and smell would have made the
13 food unmistakably inedible.

14 But what about cattle, chickens, hogs? If they
15 had grazed or fed on contaminated food, would the dioxin
16 be contained in the meat or fat? Studies are currently
17 under way to determine if dioxin enters and moves up the
18 food chain. While the results are still uncertain, uptake
19 in domestic animals has not been shown to result in signifi-
20 cant human exposure.

21 It is impossible to estimate how much herbicide
22 may have been in the water in Vietnam, but it is safe to
23 assume that run-off from the jungle or actual river bank
24 spraying did contaminate some bodies of water to some
25 degree. Herbicides and dioxin tend to settle out in water

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1 since they do not dissolve in water, and have a higher
2 specific gravity.

3 The particles of herbicides sink to the bottom
4 and once settled in the silt at the bottom tend to persist.
5 Whether this exposed you to Agent Orange is impossible to
6 say. It depends on the water supplies you drank from. As
7 with food, the odor and the look of herbicide Orange in
8 water would have been very offensive. You probably would
9 not have wanted to drink the water.

10 In a moment we are going to talk about the medical
11 effects of herbicide and dioxin exposure as much as is
12 known , the long- and short-term symptoms, what the VA
13 plans to do and is doing and what you should do if you
14 think that you might have been exposed in Vietnam.

15 We mentioned earlier that dioxin is a very toxic
16 chemical. For this reason, humans cannot be intentionally
17 exposed to dioxin for scientific studies. Researchers,
18 then, have had to work with animals. From laboratory mice
19 to Rhesus monkeys there have been many studies. Some of
20 them have been very well conducted and have provided clues
21 to the possible effect on humans.

22 Laboratory studies have shown that dioxin expo-
23 sure causes cancer, birth defects, weight loss, skin
24 lesions in some animals. The major difficulty with animal
25 studies is that you cannot directly apply the results to

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1 humans. For example, these studies often use extremely
2 high doses or unusual methods of exposure like direct
3 injection. Animals studies give some insight into the
4 possible chemical effects in man, but it is misleading to
5 make direct comparisons between humans and animals.

6 And so, the body of information on the effects
7 of these chemicals on humans has had to come from the
8 study of positively documented cases of direct exposure.
9 While these studies are not as complete as scientists and
10 researchers would like, they have given us some preliminary
11 glimpses into what we might expect and they provide the
12 only real look into the health effects of dioxin contami-
13 nation, but, like the animal studies, it is impossible to
14 draw one-to-one comparisons between these accidents and
15 the types of exposure that were likely to occur in Vietnam.

16 For one thing, concentrations of dioxin in the
17 herbicides used in Vietnam were much less than these acci-
18 dents. Also, the exposure in Vietnam was probably less
19 direct. Nonetheless, toxic effects occurring shortly
20 after heavy exposure to dioxin are well known and well
21 documented as a result of these industrial studies.

22 We are going to break our description of symptoms
23 into two categories, acute, meaning those symptoms that
24 occur soon after exposure, and chronic, meaning those
25 symptoms that persist over a long period of time. Let's

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1 start with the acute symptoms. Again, some of these
2 symptoms are well known and documents from proven human
3 exposure to dioxin in industrial accidents.

4 Physical symptoms include tingling in the hands
5 and feet, aching in the joints and muscles, headaches,
6 nausea, a skin condition, chloracne, and general weakness.
7 Other less specific symptoms are weariness, loss of drive,
8 and perceived personality changes; for example, an increased
9 tendency to lose one's temper or irritability.

10 With the exception of chloracne, these symptoms
11 generally tend to clear up by themselves and in a short
12 period of time.

13 As for chronic or long-term effects, the only
14 condition which has been absolutely linked to dioxin is
15 chloracne. Since chloracne resembles common acne in appear-
16 ance, it is often difficult to diagnose and may require a
17 special examination by a dermatologist.

18 Chloracne is generally considered to be evidence
19 of exposure to dioxin. In fact, some scientists believe
20 that humans without chloracne probably have not suffered
21 the toxic effects of TCDD or dioxin. Vietnam veterans have
22 experienced many kinds of skin diseases. Most of these
23 problems are quite common and would not prove herbicide
24 orange exposure. It is important not to confuse other skin
25 conditions with chloracne. A physician will have to make

1 that diagnosis.

2 Several changes in other body systems have also
3 been suggested as possible long-term effects of dioxin
4 exposure. There are no positive findings as of right now,
5 but research is continuing. From a review of past experi-
6 ences with herbicides, these are the body systems of con-
7 cern to researchers at this time: the skin, liver, the
8 nervous system, the reproductive system. A few reports
9 have suggested the possibility that herbicide or dioxin
10 exposure might cause psychological changes, birth defects,
11 or even cancer, but it is important to remember that right
12 now there is still no definite scientific proof.

13 At this time the data that are available do not
14 warrant any kind of panic reaction or radical treatment.
15 At the present time there is no good scientific evidence
16 linking birth defects in the children of Vietnam veterans
17 to herbicide exposure.

18 The time bomb theory that dioxin is stored in
19 your fat cells waiting to be released if and when you lose
20 weight has not been scientifically proven. It is probably
21 more harmful to your health for you to be overweight. Stay
22 in good physical shape. Keep up your exercise.

23 You may feel frustrated and disappointed that you
24 still aren't getting absolute answers to your questions
25 and concerns about Agent Orange, and, frankly, the VA shares

1 that disappointment, but no one can give you all the
2 answers when no answers exist. That doesn't mean, however,
3 that the VA is unconcerned or idle. In fact, the VA is
4 actively engaged, not only in providing examination, care,
5 and treatment, but also in research, information gathering,
6 and cooperation and participation with other agencies
7 probing the herbicide issue.

8 In April of 1978 in response to rising concern
9 about the health effects of herbicide use in Vietnam the
10 VA formed an advisory committee on the health-related
11 effects of herbicides. Its purpose was to exchange infor-
12 mation about herbicides and the possible health effects of
13 exposure and to advise the VA on future courses of action
14 including research.

15 The VA is also currently reviewing all of the
16 world literature on herbicides and dioxins, but committees
17 and literature reviews, as important as they are, may not
18 mean much to the veteran who thinks that he or she might
19 have been exposed to Agent Orange and may be suffering from
20 the effects.

21 When you have a medical problem you consider
22 related to herbicide orange, let the VA examine you. If
23 you have a technical question on Agent Orange, ask advice
24 of your VA medical center or clinic. If you want to file a
25 claim for any health problem, you can get help from the VA.

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1 Try not to be alarmed by hearsay. The Agent
2 Orange coordinator, also called environmental physician,
3 at your nearest VA medical center is one of your best
4 sources of information. If you have filed a claim related
5 to Agent Orange or you are examined by the VA, any disa-
6 bility will be researched for a possible link with military
7 service, Agent Orange or otherwise.

8 Results of your examination will be put in your
9 permanent file for possible use in supporting any future
10 claim you file. Data from your examination will be corre-
11 lated with those of other veterans in search for common
12 problems. If such problems are found, the VA will be able
13 to contact you for a follow-up evaluation.

14 In addition to the above, compensation may be
15 available if you have a disability incurred or aggravated
16 by military service. The only requirement is that the
17 disability be confirmed and it must be related to the time
18 period that you were in military service. There is no
19 requirement to link it to a specific cause such as Agent
20 Orange.

21 When you come to a VA medical center or outpatient
22 clinic and say that you might have been exposed to Agent
23 Orange, you will be asked to help fill out a questionnaire.
24 You will be asked when you were in Vietnam, what your job
25 was, where you were stationed, what your health was like

1 while you were in-country, what you've been doing since
2 Vietnam, and similar questions.

3 It is not the purpose of this questionnaire to
4 establish eligibility for care or compensation. The VA is
5 not interested in this information for purposes of either
6 granting or refusing treatment. The information gathered
7 will be entered into a central computer where it will form
8 the basis of the Agent Orange Registry. More about this
9 registry in just a minute.

10 After you have helped gather this information,
11 you will be given a complete, thorough physical examination,
12 not just an examination for what your symptom or complaint
13 is, but a total physical that will examine all body systems.
14 Even if you do not have symptoms you will be given this
15 examination.

16 The results of your physical, the laboratory
17 tests you received, and the information gathered from the
18 questionnaire, will all be entered into the Agent Orange
19 Registry that we mentioned earlier. Any veteran who
20 served in Vietnam who wishes to, will be examined and
21 entered into this Registry. The data may be supplemented
22 as needed over the years through a series of follow-up
23 examinations performed by the VA. This data will be
24 analyzed on a regular basis in order to detect any signifi-
25 cant trends or changes in the health of these veterans or

1 to determine if any particular diseases are occurring with
2 an unusual frequency.

3 This Registry will also allow the VA to keep in
4 contact with you and other Vietnam veterans possibly ex-
5 posed to Agent Orange.

6 If there are relevant breakthroughs or discover-
7 ies regarding either diagnosis or treatment, you can be
8 contacted and promptly advised of the new findings.

9 The VA is also participating in the Armed Forces
10 Institute of Pathology Registry. The purpose of this
11 Registry is to collect and review tissue material obtained
12 during surgical procedures and autopsies on Vietnam veter-
13 ans. These tissues are sent to the Armed Forces Institute
14 of Pathology where they are evaluated and reviewed. A
15 report of the findings is then submitted to the VA. The
16 tissues are retained at the Institute so that they may be
17 used for further studies as needed.

18 Some of the studies being considered are the
19 detection of unusual or unique tumors , the search for an
20 unusually high incidence of a tumor from a particular part
21 of the body or occurring at an unusual age, or the discov-
22 ery of a group of similar cases in a particular military
23 unit.

24 In addition to participating in these date-
25 gathering activities, the VA is involved in several

1 educational efforts, not only for veterans but also for VA
2 health care personnel. This television program is a part
3 of that effort. Another program provides VA health care
4 personnel with the latest scientific and clinical informa-
5 tion on Agent Orange.

6 The VA is developing a program for statistical
7 analysis of the Agent Orange Registry and hopes to compare
8 the health of those in the Registry with the general popu-
9 lation. The VA also plans to conduct a scientific study
10 of Vietnam veterans who may have been exposed to herbicides.
11 This study will try to determine if there are specific
12 herbicide-related health effects within the veteran com-
13 munity.

14 It is hoped that the preliminary results of this
15 study will be available in the next two or three years.
16 The VA is also following several specific research areas
17 which include the study of toxic effects in the laboratory
18 animals and birth defects in mice. The VA will continue
19 to cooperate with other agencies, individuals, and groups
20 who are studying the herbicides.

21 It is you, the Vietnam veteran, who has the
22 biggest stake in the Agent Orange issue. The VA was
23 playing a leading role in gathering all the facts, and we
24 are depending on you for help. If you served in Vietnam
25 and have reason to believe that you have been exposed to

1 herbicides, come to a VA medical center or outpatient
2 clinic and participate in the Agent Orange Registry. If
3 you have physical problems or complaints, the VA wants to
4 know about them and help in any way it can. You can assist
5 the VA by bringing any medical record which you may have,
6 both civilian and military. These records may show that
7 you have sought treatment for ailments in the past that
8 might relate to herbicide or dioxin-related problems.

9 In addition to being helpful to the Registry,
10 this information may be helpful in determining your eligi-
11 bility for treatment and compensation.

12 The controversy surrounding Agent Orange will
13 probably continue for some time yet, and the VA will con-
14 tinue to support you in every way possible, exploring new
15 avenues of research, providing thorough examinations and
16 follow-ups as needed, and disseminating any and all new or
17 important information.

18 If you would like more information about Agent
19 Orange, contact your nearest Veterans' Administration
20 Medical Center or Regional Office. If you have any ques-
21 tions about general benefits or compensation, contact a
22 representative from the Department of Veterans Benefits.
23 In addition, veterans' service organizations can provide a
24 wide range of assistance and information.

25 The process is long and frustrating, and sometimes

1 it seems that not much headway is being made, but every day
2 brings us closer to the answers.

3 Do your part. Contribute to the effort. Keep
4 informed. Keep in good health. Keep in touch. If you
5 are still in contact with buddies from Vietnam who are
6 worried about Agent Orange, tell them about the VA's pro-
7 gram and ask them to get involved with the Registry.

8 The questions are complex and the answers are
9 few. Cooperation and understanding from the VA and you
10 are valuable first steps in coming to terms with Agent
11 Orange. Our greatest hope lies in the resources we share
12 together.

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1 DR.SHEPARD: Okay. Let me just say one
2 thing about things that will be changed. Some of the word-
3 ing on the description of the registry, which we've
4 talked about. There was a statement to the effect that
5 these data will be scientifically analyzed and compared
6 to other groups. That isn't accurate, and that's being
7 changed, to more accurately reflect my earlier comments
8 about the registry. That is being changed.

9 Now, do you have any comments? Yes, Dr. Murphy.

10 DR. MURPHY: One thing that I sort of felt was
11 not emphasized, and I think it might be helpful, is this
12 idea of preventing panic, if you will. And that is there
13 was little or no discussion of the relationship of dose.
14 The implication was either you were exposed or you were
15 not. But how much you were exposed, of course, is an
16 important factor, as well, as to whether one sustained an
17 injury or not.

18 I thought that was not brought out as much as
19 it might have been as a part of that.

20 MR. DeYOUNG: Thinking back, I can recall some
21 discussion on it in the original content meeting. And
22 I'm not sure whether it was consciously decided to drop
23 it, or whether it went through attrition, because I don't
24 think we could achieve some sort of unanimity about what
25 kind of statement to make about dose relationship.

1 If anyone here could make a statement that we
2 can all live with, I think we could include it. I can
3 remember comments being made during the development of it
4 that it was not a clear-cut dose response relationship
5 in laboratory studies. And in the field the question was
6 raised by the Air Force: how do you define a dose, you
7 know, what is the model here. So it got very, very
8 muddy.

9 DR. MURPHY: This is a principle, not a fact
10 that you are dealing with. All toxic effects are dose-
11 related. I suppose you could disagree with that a little
12 bit as far as allergic reaction.

13 MR. DeYOUNG: As a general statement, it's true,
14 though.

15 DR. MURPHY: The other thing that I was a lit-
16 tle concerned by: Just before or while this was going on
17 I was going this memorandum that was distributed.

18 I was struck by the responses, as small sample
19 as it is, the responses that told how little the physi-
20 cians seemed to know.

21 One thing -- and, again, I may have missed some-
22 thing right at the beginning -- but this compound was
23 referred to as dióxin and TCDD, and to my knowledge never
24 referred to as tetrachloridibenzo. 2,4,5-T was
25 called phenoxy herbicide, never chloral phenoxy herbicide.

1 To most physicians, ignorant as they might be about these
2 particular things, chloral is something that I think --
3 let the physicians answer about that -- keeps their
4 attention a little bit. They know something about
5 chloral. And that was never brought out.

6 Now, I recognize this is not for the physician
7 community. But I think it wouldn't hurt, perhaps, to
8 educate your veterans that dioxin is just, you know, sort
9 of a very loose term. And I'll tell you a story that
10 the first time I heard about this, my boss at that time
11 came and asked me, "What do you know about this dioxin
12 that somebody just discovered?" And it took me several
13 weeks to figure out what he was talking about, because
14 when you go look up "dioxin," or once upon a time when
15 you looked up "dioxin," you didn't find it. You found
16 "dioxane." You had a hell of a time finding it.

17 I think a little bit more precision in term-
18 inology, even though you have to, of course, use the
19 common terminology, it wouldn't hurt to incorporate it.
20 Maybe not this film, but certainly in a physician-educat-
21 ing film.

22 MR. DeYOUNG: The position we all finally fell
23 back to was, "Well, this is what the veterans community
24 knows it as." You know, "Let's talk in the language
25 they'll understand," and make an attempt to at least clear

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1 up the fact that not all herbicides were Agent Orange,
2 and that it's kind of a generic noun for the six actual
3 colors that were used, and so forth.

4 We dealt with that, although you're right, we
5 did not ever say tetrachloral bibensodox, and so forth.

6 DR. SHEPARD: I think your comment about
7 education, first of all, we had some time constraints to
8 make this a useful thing. And so there was probably some
9 detail that was not used.

10 The question of the understanding of the target
11 audience: In trying to focus on the issues that were of
12 prime concern, I think it's safe to say, first of all, we
13 are not, as Layne indicated earlier, we are trying to
14 develop educational tapes for physicians that will go
15 into considerably more depth on the thing, and hopefully
16 some of that will spill into the veteran community, as
17 well. So that we won't just be getting physicians, but
18 other individuals interested in the program.

19 Yes, sir.

20 DR. GROSS: I see this videotape as having sort
21 of a dual purpose. First of all, to allay fears, panic,
22 whatever; and, also, to help per se the veterans to come
23 in, register and submit to examination, and so on.

24 I wonder if it wouldn't have been proper, along
25 with the first objective, to have stated, perhaps, that

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1 for those people, the Operation Ranch Hand types were
2 certainly exposed to massive levels of this, but that in
3 fact many serious health effects have not been indicated
4 so far.

5 DR. SHEPARD: Yes.

6 DR. MURPHY: Well, I think some people have a
7 question whether they had the most exposure. That's come
8 up before. I don't know if anybody is sure they did.

9 MR. DeYOUNG: Well, this again was discussed in
10 the development. And it was agreed that it was the most
11 probable high exposure level.

12 I personally feel that the GIs in the field may
13 have received a good deal higher dose through the water
14 and ambient contamination than we imply in this tape.
15 It's never stated specifically. It really does try to
16 walk a fence at times; there's no question about that, to
17 me.

18 I think if we fall off the fence it's on the
19 side of conservatism. Rather than saying, "Oh, my Lord,
20 this could have done all sorts of horrible things to you,"
21 we say, "Well, it probably didn't or you would know it by
22 now." It's that kind of implication.

23 My recollection is that the Air Force representa-
24 tives were quite insistent that the Ranch Hand people
25 had the model for high probability of exposure.

1 DR. GROSS: In quantity.

2 MR. DeYOUNG: In quantity and repeated doses
3 and such, yes. There's no question that there could be
4 an isolated incidence of a man ingesting an amount of it,
5 you know, from a dump, instead of an actual spray opera-
6 tion, or something like that.

7 DR. LINGEMAN: I'd like to know if the veterans
8 in this combat area were aware of this, I understand, very
9 penetrating odor? And did the veteran usually know what
10 it was? Did he ask, "What is that stuff we're smelling?"

11 MR. DeYOUNG: The common answer was it was bug
12 spray, or weed killer -- generic stuff of that nature.

13 DR. GROSS: Defoliation, they knew about de-
14 foliation.

15 MR. DeYOUNG: Oh, certainly. It was accepted
16 knowledge at the time. But it was the kind of thing that
17 was like when we leave this meeting, someone may ask you
18 what color the walls were. And although you knew there
19 were walls in the room, you may not have noticed what
20 color they were and you may not recall it, because all
21 rooms have walls, and all jungle operations had defoli-
22 ants. It was that kind of thing. Nobody looked twice
23 to see what the chemical was.

24 And certainly no one was specifically inter-
25 ested in the scientific names of the chemicals, and so

1 forth. It was weed killer.

2 DR. SHEPARD: Does that answer your ques-
3 tion, Carolyn?

4 DR. LINGEMAN: Well, I just talked to a woman
5 who claimed that the forest near her house was sprayed,
6 and she said, "Oh, this odor was horrible; it smelled
7 sort of like vinegar and it came out and spread across
8 the whole area." I wonder if the veterans themselves
9 could distinguish these odors? Were they aware of a
10 vinegar-like odor? Or was it sort of a hazy idea that
11 these were chemicals? Did anyone ask them, "Could you
12 smell this vinegar-like odor?"

13 MR. DeYOUNG: I don't recall anything as
14 specific as vinegar. "Chemical stink," "horrible smell"--
15 those kinds of things -- much, much less specific than
16 "vinegar-like smell."

17 I'm not sure we could be that specific.

18 DR. LINGEMAN: In designing our questionnaires,
19 we came across that question. What do we ask them?
20 "Were you aware of herbicides being used?" Were you a-
21 ware of chemicals being used?" "Do you know what the
22 chemicals were?" Is that the way we should ask the
23 question?

24 MR. DeYOUNG: You may get very few positive
25 answers to those questions, no matter how you ask them,

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1 because the average GI would simply not know what it was.
2 He may remember things like a horrible odor, but telling
3 the difference between malathion odor and Agent Orange
4 odor, that's another story entirely.

5 DR. SHEPARD: I think we might be of some
6 help to you in formulating some of your questions, be-
7 cause we had the experience of the current registry ques-
8 tions, and I think we have a fairly good idea as to what
9 questions have been productive and what questions haven't
10 been. So I think maybe we can get together on those.

11 DR. LINGEMAN: We don't want to suggest -- I
12 think there is a way to word a question so that you don't
13 put words in their mouths.

14 DR. GROSS: Good idea.

15 DR. SHEPARD: Yes, sir. In asking ques-
16 tions, may I suggest that you identify yourself.

17 MR. BOCHICCHIO: Bochicchio, American Legion.

18 Reference was made to probably the highest
19 vulnerability to the exposure of Agent Orange referred to
20 the Ranch Hands, consisting of approximately 1200. Do we
21 have any record at all of how many of these so-called
22 1200 have come in so far and have indicated a malady or
23 a complaint about their physical condition and allegedly
24 maybe saying that it may have been caused by exposure to
25 the herbicide?

1 DR. SHEPARD: I'm sure the Air Force has
2 some feeling for that. I don't have any hard data or even
3 soft data. I have asked that question of people in the
4 Air Force, and I have the impression that they are not
5 aware of any increased incidence of either complaints or
6 documented problems among the Ranch Hand group.

7 MR. BOCHICCHIO: I have not only an official rea-
8 son for asking the question, but my son was a pilot and he
9 flew and sprayed herbicide in a 123 for close to 13 months,
10 and he's yet to be contacted by any group. And we are
11 hoping that some day he might be.

12 DR. SHEPARD: Is he on active duty?

13 MR. BOCHICCHIO: No, he is not on active duty.

14 DR. SHEPARD: I feel confident that the Air
15 Force will very shortly be contacting the identified
16 members of the Ranch Hand group.

17 You say he was actually involved in the spraying
18 missions?

19 MR. BOCHICCHIO: Very definitely. And inciden-
20 tally his former commanding officer is sitting right there
21 in the corner.

22 DR. SHEPARD: Yes. I'd like to recognize
23 Colonel Charles Hubbs, who is a technical advisor to this
24 Committee, and was himself in Vietnam, and as I understand,
25 was involved in the Ranch Hand operation there.

1 Perhaps you would like to have a word or two,
2 Colonel.

3 COLONEL HUBBS: I don't have any comment. Thank
4 you.

5 CHAIRMAN SHEPARD: Okay. Nice to have you here.
6 Yes.

7 MR. ENSIGN: My name is Tod Ensign, with the
8 Citizen Soldier organization. This is the first chance
9 I've had to see the film, so I have a lot of reactions.
10 But there are two that strike me that I think border --
11 they are omissions that border, I think, on distortion of
12 the record, serious distortion.

13 One is the fact there is absolutely no mention
14 of the fact that the program was ceased in 1970 or '71,
15 according to some accounts, because of a major interna-
16 tional controversy over the health effects, particularly
17 upon the Vietnamese civilian population.

18 I think that's a pretty serious omission. And
19 parenthetical to that is the fact there is no mention of
20 the fact that Dr. Tung, among other Vietnamese scientists,
21 has published a number of studies which demonstrate
22 certain human health effects. He has one now that has
23 been completed that is undergoing review for publication
24 in this country.

25 The second part of it is, and even more offen-

1 sive to me, is the implication that there's no controversy
2 in this country over the widespread use of this in domes-
3 tic agricultural and forestry operations. And I think
4 when you consider that the EPA only for the second time
5 in its history used its emergency powers to withdraw
6 2,4,5T from most use in this country in March of '79, I
7 think that certainly is an omission -- I realize the
8 purpose of this is to reach veterans and talk to them
9 about the problems they uniquely experienced, but I think
10 that there should be some recognition of the domestic con-
11 troversy and the international controversy over the uses
12 of these compounds even right up to the present time.

13 DR. SHEPARD: Thank you. I think, again,
14 I agree, I think that we could have emphasized more^{of} the
15 controversy. I think, however, that our con-
16 cern for allaying concerns or avoiding raising unnecessary
17 concerns is something we have to keep in mind, also. And
18 if one emphasizes or highlights controversy without going
19 into considerable depth and evaluating the controversy
20 and coming up with a bottom line which may not still be
21 there, which isn't there, really-- that part of our goal
22 in this may have been overtaken.

23 DR. MURPHY: Dr. Shepard.

24 DR. SHEPARD: Yes, sir.

25 DR. MURPHY: I would think that you are walking

1 a very narrow line there to achieve that without losing
2 credibility. And that's why I think you've got to be
3 very careful. You know, it isn't going to do any good
4 if the target population says, "Well, you know, we've
5 talked to scientists and we've read this, and you don't
6 even mention it."

7 I think, you know, sometimes you might have to
8 do a little explanation and educating as to details.

9 DR. SHEPARD: Yes.

10 DR. MURPHY: That's another thing I didn't
11 mention before that I thought was somewhat of an omission
12 and played down was the implication that you can't make
13 any direct -- and that's true, in a sense -- extrapola-
14 tion from animals studies to human effect. But a lot of
15 the animal studies are causing people to ask the questions.
16 And, you know, if you say it doesn't really mean anything--

17 DR. GROSS: I thought this was mentioned in the
18 film. There was a clear statement that TCDD is a highly
19 toxic material. And this is well known and animal stud-
20 ies are available. I looked for that myself, and I
21 thought I saw it in there.

22 DR. MURPHY: Well, there's a difference of
23 opinion on how much.

24 DR. SHEPARD: One thing I might say. I
25 hope part of the use of this film will be to stimulate

1 discussion, and hopefully veterans seeing this film will
2 then grasp the opportunity to discuss some of the issues
3 and some of the unanswered questions with environmental
4 physicians and other individuals in the medical centers.
5 And I hope this will serve as a tool to open up a dia-
6 logue. I think this would be helpful.

7 MR. DeYOUNG: I have a specific question that
8 I would like to get a few responses to, at least. I'd
9 like some opinions on the scientific validity of the
10 section that discusses the photo-degradation in sunlight
11 of dioxin. This is a piece of --

12 UNIDENTIFIED SPEAKER: Self-study.

13 MR. DeYOUNG: Yeah. It's documented in a number
14 of different ways. I mean I have studies given to me by
15 various people that purport to prove that it breaks down
16 very quickly in sunlight, and that when you put it in
17 shade or under water, it persists for a much longer
18 period of time, and so forth.

19 Is there any commonality? Is there any con-
20 sensus in the scientific community as to where we are on
21 this?

22 The bottom line question is: Is the tape mid-
23 dle-of-the road scientifically sound in saying, first,
24 that it begins to degrade very quickly in sunlight? The
25 implication given by that passage is that it becomes

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1 safer the longer time goes on.

2 And secondly, the passage that discusses the
3 jungle intercepting the herbicide and the dioxin before it
4 gets down to the jungle floor, and, therefore, the
5 chances of contamination were slight, or something like
6 that.

7 Is there any reaction to these?

8 DR. GROSS: I thought it was proper because it
9 is known that this is a fact now. How specifically well
10 documented it is, we don't know.

11 On the other hand, no claim was made. They
12 talk in general about chances. I remember the arrows
13 with only a small part within, and there is no reason to
14 doubt that. It does degrade. Under the action of light
15 there is photo-degradation. But how much, there was no
16 claim being made here specifically.

17 MR. DeYOUNG: There was no specific claim. But
18 it strikes me that the implication of the passage, how-
19 ever, is that a relatively short amount of time renders
20 it much less harmful than it originally was. Is that
21 an appropriate statement?

22 DR. MURPHY: Well, I don't know.

23 MR. DeYOUNG: I don't, either. I have some
24 reservations about this passage.

25 DR. MURPHY: Sure it does. A relatively short

1 amount of time renders a monomolecular layer of that
2 pretty quickly. You know, it degrades, detoxifies
3 quickly under sunlight. But I don't know how fast the
4 whole residue would degrade, if there was a residue there.

5 I think that there's no real scientific error
6 in what was said there. I think it's a matter of empha-
7 sis and a matter of degree. I had somewhat of a sense
8 that you were implying, you know, in two or three days
9 with the sun shining on a defoliated area, it would be
10 gone. I doubt that that would be the case. It might be
11 after two or three weeks.

12 MR. DeYOUNG: Thank you.

13 DR. SHEPARD: There is research being done
14 on that, though. In the Rome meeting there were some
15 references to photo-degradation. Although I can't put
16 my finger on it right now, it is an area under scientific
17 investigation. And there was nothing said in Rome that
18 would not go along with what is said here.

19 DR. ROSS: I would like to comment on that,
20 also. I paid particular attention to that. I think that
21 in a general sense, I think it was a very straight-forward
22 end to the film that if the majority of the spray remained
23 on the foliage, and depending on the climatic conditions,
24 whether it was a rainy day or cloudy day, certainly if it
25 was a very bright day, most of the dioxin, yes, would de-

1 grade on the foliage. But I think the literature also
2 substantiates that a residual part of it would go to the
3 ground and combines very readily with the soil and it has
4 a much, much longer half-life.

5 So the question there would lie, how thick the
6 jungle would be, how much would remain on the foliage,
7 and so forth.

8 I think that you would probably get a majority
9 with maximum exposure on the foliage, which, indeed, I
10 think your film accurately reflects that.

11 MR. HANSON: My name is John Hanson. I have a
12 couple of observations and a couple of questions.

13 One, the videotape, in discussing the different
14 methods which were used to spray Agent Orange from trucks,
15 back-packs, airplanes, and the like, said that it was used
16 to clear some base camp perimeters..

17 I think that perhaps that is not an accurate
18 indication of the degree to which base camp perimeters
19 were sprayed. I think you will find that probably most
20 base camp perimeters were sprayed. Not all were sprayed
21 with Agent Orange; some were sprayed with Agent Blue,
22 which is cacodylic acid. Of course, it's an arcetic.

23 So I think that perhaps that is not an accurate
24 characterization of the use of herbicides to clear base
25 camp perimeters. The first hundred meters outside any

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1 base camp was a free spraying area. There was no required
2 approval for it to be sprayed, and it could be sprayed any
3 time the commander in charge wanted it sprayed.

4 I think that perhaps ought to be looked at as
5 to whether or not you ought to change that in the tape.
6 I believe the tape said it was used to clear some base
7 camp perimeters. What I'm saying is I think a more
8 accurate statement would be that it was used to clear most
9 base camp perimeters, because I certainly don't think that
10 you want to mislead a veteran who was inside a base camp
11 and spent most of his time there, so that if only a few
12 base camp perimeters were sprayed, it may diminish his
13 potential for having come in contact with herbicides.

14 Second, the tape does mention some of the animal
15 studies that have been done and some of the findings in
16 the animal studies, and does point out that while there
17 have been some good results here-- and I'll try and state
18 this as close to the tape as I can -- that the animal
19 tests may be misleading indicators of human effects.

20 I think that's pretty close to what the tape
21 says. I think the word "misleading" was used in there.
22 However, at the end of the tape, when you go into the
23 section that talks about what the VA is doing, one of the
24 things it said that's doing is helping to conduct more
25 animal tests.

1 Well, in the tape you're telling the veteran,
2 on one hand, that animal tests, while they might be
3 interesting, are misleading indicators of human
4 effects. And my question is: Why does the tape at the
5 end say, you know, the VA is involved in having more
6 animal tests conducted?

7 I'm certainly not questioning whether
8 animal tests are useful or not. I'm saying that there's a
9 basic inconsistency in the tape with regard to your views
10 on the value of animal test results.

11 DR. SHEPARD: Will you check that?

12 DR. GROSS: I didn't hear the word "misleading."

13 DR. SHEPARD: I didn't, either.

14 DR. GROSS: Because I would have violently
15 objected had I heard that.

16 MR. HANSON: Well, perhaps I mischaracterized
17 it. But I think the tape made it very clear that animal
18 test studies, they cast a lot of doubt on their applica-
19 bility to human health effects, or even as an indicator of
20 human health effects.

21 MR. DeYOUNG: I can give you the quote, if you
22 like: "Animal studies give some insight into the possible
23 chemical effects in man, but it is misleading to make
24 direct comparisons between humans and animals."

25 DR. GROSS: That's a little different.

1 MR. DeYOUNG: It's been changed a little since
2 then and I'm not sure exactly how.

3 DR. GROSS: I would object to this statement.

4 MR. HANSON: You know, it's interesting, but the
5 the question is, what are human effects? We know what
6 effect it has on some species of animals that it's been
7 tested on. But if the question is human effects, and the
8 tape states it is misleading to apply--

9 MR. DeYOUNG: Directly apply.

10 MR. HANSON: To directly apply animal test re-
11 sults to humans, I would certainly raise a question at the
12 end: Why is the VA going to spend money doing more
13 animal tests when they have already said in the tape that
14 they may not be good indicators of humans? Why isn't that
15 money being spent to focus on human health effects prob-
16 lems?

17 DR. SHEPARD: Animals are first.

18 MR. HANSON: I realize that, Dr. Shepard. I'm
19 not questioning that. But I'm saying I think it's mis-
20 leading.

21 DR. MURPHY: Of course, I'm a little defensive
22 about this, too, being an experimental toxicologist and
23 not believing epidemiology ever gives you a conclusive
24 answer. I just think it's bad practice to give the im-
25 plication that you can't, that animal tests don't have

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1 some pretty important function in interpreting human
2 health effects.

3 So I would hope this could be softened as much
4 as possible. Mr. Hanson is bringing this out.

5 Another aspect of this is you are going to
6 turn this around and use animal data to support the indica-
7 tion that birth defects don't seem to be happening, or
8 don't seem to be a likelihood. You know, you can't--

9 DR. SHEPARD: You can't have it both ways.

10 DR. MURPHY: That's right.

11 DR. GROSS: Well, I just hate to say that
12 animal findings are misleading indications as perhaps too
13 strong. You may question the relevance of animal find-
14 ings, which is all right. But to actually go as far as to
15 state they are misleading, that would be a misleading
16 statement itself.

17 MR. DeYOUNG: We'll look at a constructive
18 clean-up on that one.

19 MR. HANSON: Let me make a couple of other ob-
20 servations, if I might.

21 A previous questioner mentioned that there was
22 nothing in here to indicate that studies done by Dr.
23 Tung in Vietnam had been included. And it brought to
24 mind something that I did not recall mentioned, and per-
25 haps there's a good reason why--I don't know.

1 In discussing whether or not dioxin could have
2 gotten into the food chain, I recall a study done by Dr.
3 Messleton and Dr. Vohlman at Harvard, that they had done
4 studies in Vietnam and did find traces of dioxin in fish
5 in a river in Vietnam.

6 Now, I don't know whether that study has been
7 generally accepted as some indication that dioxin did get
8 into the food chain or not. If it is a good indication,
9 then I think it might be a good idea to consider showing
10 that a study was done on it. I think to my knowledge, it
11 was the only study done on this aspect in Vietnam.

12 I don't think the scientists from the National
13 Academy can get back into Vietnam, but perhaps you ought
14 to look into whether or not that kind of information
15 should be included, as, indeed, it might be the only indi-
16 cation of whether or not dioxin could get into the food
17 chain.

18 Finally, I believe you mentioned that at the
19 request of the Administrator, certain service organiza-
20 tions were asked to comment on this tape. I have a couple
21 of questions with regard to that.

22 One, what service organizations were asked?
23 Were the same ones asked to comment on the tape who were
24 asked to comment on the draft pamphlet about Agent Orange?
25 If they weren't the same groups, why not?

1 I think that really what I'm getting at, Dr.
2 Shepard, is I think this is an important step as far as
3 the VA is concerned, and getting out its message on how
4 Agent Orange was used, what the effects may or may not be,
5 and what the Veterans Administration is doing about it.
6 Since there seems to be a very critical group of veter-
7 ans as to what the Veterans Administration has done, it
8 might be good before this tape is sent out and dissemi-
9 nated all over the country that you insure that you at
10 least listen to the comments of those types of groups.

11 I certainly think that perhaps they could pro-
12 vide some insights which may be beneficial to making sure
13 the tape is a reasonably balanced representation of the
14 body of knowledge that exists with regard to Agent Orange.

15 That's all I have.

16 DR. SHEPARD: Thank you, John.

17 Any other comments? Yes, Dr. Erickson.

18 DR. ERICKSON: A request. I became aware this
19 morning that I'm confused and it seems, perhaps, several
20 other people are confused about this registry and what
21 its purpose is. It occurs to me that we have never seen
22 anything written about the registry; we've never seen the
23 questionnaire.

24 I wonder if you could arrange for the Committee
25 to receive documents of that sort.

1 DR. SHEPARD: Certainly. I'm somewhat
2 embarrassed to think that this Committee had not been
3 provided with copies of the questionnaire. That informa-
4 tion appears, I feel confident, in some of the material
5 that you have. It may not have been ferreted out and
6 highlighted.

7 For example, I think we circulated the testi-
8 mony of February 25th to all members of the Committee,
9 and that does appear in there, Dave. But we were prob-
10 ably negligent in the fact that we haven't highlighted it.
11 And we will certainly be happy to do so.

12 The questionnaire, of course, was formulated
13 fairly early.

14 DR. GROSS: That's the questionnaire that is
15 appended here? I saw a questionnaire here some place.

16 DR. SHEPARD: I don't think it's in the
17 package you received today, but in the previous mater-
18 ials that have been provided to you, I think you will
19 have it. But certainly, anybody who wants a copy of that,
20 we will be more than happy to provide it.

21 Go ahead, Dave.

22 DR. ERICKSON: Beyond that, I wonder if you
23 have some written material describing the registry and
24 its anticipated usage. Apparently, your position on that
25 has changed from the time the tape was written to this

1 morning, and I guess my gut reaction is that either of
2 those extremes may be too severe and you might have some
3 possibility of getting something quasi-scientific out of
4 your registry.

5 DR. SHEPARD: That question has been
6 raised, and I think the temptation is to say that after
7 we get this information, we will make some analysis of it.
8 I'm not a statistician by any stretch of the imagination,
9 and perhaps I should be rapped on the knuckles for even
10 implying that that might be the case. So I'm understand-
11 ably, I think cautious about claims for the registry.

12 But, yes, we do have some descriptive material.
13 We would be happy to provide that. Yes, sir.

14 MR. SMITH: Richard Smith. In the videotape
15 was listed the various ways you could come in contact,
16 a soldier could come in contact with Agent Orange-- walk-
17 ing through a sprayed area, drinking the water, or the
18 direct contact, by handling the substance. And my ques-
19 tion is: If the substance breaks down slower once it is
20 in contact with the dirt, if you were digging in and
21 spending a lot of time in a hole, wouldn't your risk be
22 maybe a little bit more than walking through a sprayed
23 area?

24 DR. SHEPARD: Do you mean like in a fox-
25 hole where spraying had taken place previously?

1 MR. SMITH: Yes.

2 DR. SHEPARD: I think that certainly theo-
3 retically may well be the case. Again, it's a question of
4 documenting that. And how much of it, I think the point
5 has been made, and I think accurately, that relatively
6 little of the material actually got onto the ground in
7 those areas where there was thick overgrowth of jungle.
8 That was primarily the areas where it was used.

9 How much of it actually penetrated the ground,
10 I just have no way of knowing, and I'm not sure that any-
11 body has actually assayed that. Dr. Hobson.

12 DR. HOBSON: The Air Force studies that were
13 carried out at Eglin Field very carefully went into that.
14 Dioxin remains in the very top layers of the soil. So I
15 would imagine, although I am not sure, if you dug a hole and
16 threw the dirt out, you would be below the level where
17 there was much dioxin. And there was very, very little
18 there anyway. It does not migrate within the soil to any
19 extensive degree, as I recall.

20 MR. DeYOUNG: I have one last area of concern
21 to me. When the development of this script was begun, we
22 were in a pre-Hardel situation. We did not have the
23 Swedish study, some of the later things on soft tissue
24 carcinomas, and so forth.

25 I'd like to get a sense from the members of the

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1 Committee that are qualified to comment: Are these things
2 important enough to now justify some subtle rewrites to
3 include this and the fact that the AFIP study will be
4 forthcoming? Are we far enough along on that that we can
5 say something?

6 DR. SHEPARD: I'll be happy to hear from
7 other members? I have my feelings on that, but let me
8 hear from the rest of the Committee first.

9 DR. FITZGERALD: I'll approach that, if you want
10 me to.

11 DR. SHEPARD: Sure.

12 DR. FITZGERALD: I would think that that infor-
13 mation is available to the examining physicians and will
14 be stressed in the VA indoctrination of these physicians,
15 so that they would be the ones that would be looking for
16 soft tissue tumors. I think it would be kind of diffi-
17 cult to get it across to the general population to any
18 significant degree without getting scare tactics going
19 again.

20 MR. DeYOUNG: I understand that will be ex-
21 tremely difficult to phrase, because we start talking
22 about things like "significant," and all of a sudden--

23 DR. FITZGERALD: That's right.

24 MR. DeYOUNG: -- it changes its meaning, you
25 know, from a statistical to a common conversation.

1 The question that I have, of course, is: Is it
2 fair -- possibly the right word is "hide" material informa-
3 tion which may or may not be difficult to understand, but
4 at least to my personal values, it should be in there.

5 DR. FITZGERALD: I don't think there's any at-
6 tempt to hide it.

7 MR. DeYOUNG: No. If it had been meant that
8 way, I wouldn't even mention it.

9 DR. FITZGERALD: But I think here, again, it's
10 not possible to go through a symptomatology that would be
11 complete and accurate for every individual who does not
12 have technical knowledge about that symptomatology. I
13 think it's extremely important that the Veterans Adminis-
14 tration make their physician-examiners aware of the po-
15 tential incidence of soft tissue tumors so that they are
16 looking for it.

17 I think the question that goes out to the
18 veteran asking about the existance of malignancies as a
19 whole is quite appropriate.

20 DR. GROSS: Perhaps a middle ground would be--
21 and I believe that to be the case--that one is looking
22 into perhaps this kind of association. We are concerned
23 about this because of suspicions or evidence whether there
24 is increased risk. You don't have to say whether it is
25 significant or not, but efforts are currently under way,

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1 without coming to any sort of conclusion that such an
2 association has been made.

3 DR. SHEPARD: One thing that I think we
4 strive for in a tape such as this, that we hope will
5 have a useful life, is not put things in it that may be
6 changed in the near future and, therefore, bring the
7 credibility of the entire tape into question.

8 In other words, that was why, I think, the
9 business of avoiding controversy, because controversy
10 shifts.

11 DR. GROSS: Yeah, prevailing winds.

12 DR. SHEPARD: And we get an awful lot of
13 sway back and forth as to controversial areas. If you
14 build too much of that kind of thing in there, I think
15 you run the risk of limiting the usefulness of the tape
16 for providing general background information.

17 That isn't to say that we shouldn't come out
18 with a follow-up tape, an update, or other material, not
19 necessarily a tape. We tried to keep it fairly basic,
20 fairly solid information that was not likely to change in
21 the near future.

22 MR. DeYOUNG: I have one last concern. It's
23 something that does not confuse. The hand-out that Mr.
24 Thompson passed around points up that although this is a
25 very limited response, that many of the criticisms of the

1 veterans who did respond center around the environmental
2 physicians and other attending staff at the hospital.

3 In light of that criticism, I think it may be
4 incumbent upon us to go back and take a look at our state-
5 ments about the environmental physician being your prime
6 source of information to the veteran, and so forth. That
7 is a theoretical ideal; there's no question about that.
8 The question is how well it is actually coming out in
9 every instance, and I think we need to, at minimum, take
10 steps to insure that the environmental physician is well
11 informed and presents the image of being well versed.

12 DR. FITZGERALD: Ron, I think I would like to
13 answer that, again. And that is that, yes, this is a
14 concern to the veterans service organizations as to how
15 the individual veteran is being received, how his com-
16 plaints are being taken care of. And each of these
17 service organizations have memberships that are pursuing
18 this. And indeed, if there is an individual hospital
19 where this is occurring, we want to know about it, and
20 then we send our membership out there to assure that the
21 proper care is being received by that veteran.

22 We have done this on at least one incident at
23 a hospital and found that the information that was
24 originally portrayed was not necessarily completely borne
25 up. The individuals who would be complaining quite

1 frequently are the ones who have a cause that they are
2 trying to pursue and do not necessarily, unfortunately,
3 represent the majority of individuals that are being seen
4 at that hospital. So we have to be sure that we are
5 dealing with a factual situation and not an emotional
6 situation.

7 Yes, we do pursue this very vigorously, the
8 same way we do for the treatment of the veteran for any-
9 thing, not related to environmental or anything else.
10 And we are specifically asking from our membership for
11 incidents of this nature so that we can examine it.

12 DR. SHEPARD: Thank you.

13 Tod, you sent up some questions earlier. Did
14 you want those dealt with now, or can I get back to you?
15 I think I can answer them fairly quickly, but maybe I
16 can talk to you separately. Or would you like for them
17 to be part of the discussion?

18 MR. ENSIGN: I would like to have them part of
19 the discussion.

20 DR. SHEPARD: Okay. Tod Ensign from
21 Citizen Soldier asked the following three questions:

22 "This past week I was told by Dr. James Dwyer
23 and Bob Smith of the State University of New York, Stony-
24 brook, that they have heard nothing from any member of
25 this panel as to the preliminary study they have conducted

1 on 1,313 Vietnam veterans who completed our medical
2 questionnaire." "Our" being a Citizen Soldier question-
3 naire, I presume. "As you know, their findings suggested
4 a causal link between exposure to herbicide in Vietnam
5 and ailments long associated with exposure to TCDD.

6 "I would like to know what plans, if any, this
7 panel has for consulting and cooperating with Dr. Dwyer
8 and Dr. Smith so that the maximum scientific benefit can
9 be obtained from human health data we have collected on
10 5,000 Vietnam veterans."

11 First of all, I'm not aware that we were sent
12 this material. It's my understanding that this material
13 was sent to the inter-agency work group and is currently
14 under review or to be reviewed by the scientific panel of
15 the inter-agency work group.

16 If that answers your question, I think that I
17 have heard from the inter-agency work group and I under-
18 stand that this will be a subject on the agenda for the
19 upcoming meeting. We'll be following that with great
20 interest.

21 The second question: "In a recent newspaper
22 which we sent to 14,000 Vietnam veterans we mentioned the
23 herbs-tapes and their value in tracing exposure history
24 for individual veterans. A large number of veterans have
25 called to ask how they might gain access to this record.

1 Have you given any thought to possibly making a copy of
2 the herbs-tapes along with detailed maps of Vietnam avail-
3 able at each of your 172 medical facilities?"

4 The herbs-tapes themselves are, as you
5 know, are the data on the spraying missions that took
6 place in Vietnam. I think it is not accurate to say that
7 they deal with individual veterans. They talk simply
8 about the sprayed areas. I think to make a correlation
9 between the tapes and individual veterans would have to
10 require a unit diary history indicating where the unit
11 operated and at what time.

12 The matter of giving thought to maps of Vietnam,
13 we haven't, at least I haven't, taken that into considera-
14 tion. Maybe other members of the Committee have thought
15 about it. I'm not sure, other than general geographical
16 information as to where in Vietnam the herbicides were
17 used--that certainly could be done. To include on that
18 map such information as to when the spraying missions
19 were conducted in each area of Vietnam, I think becomes
20 a little more complex.

21 Certainly I think that any veteran or any
22 group of veterans who are interested in knowing about
23 where the spraying missions occurred, that information is
24 available, and I'm sure we would be happy to share it.
25 The Department of Defense, of course, is the agency that

1 has the most detailed and accurate information in that
2 area. They have made it available to us.

3 But I think to make it, you know, a general
4 distribution, I think might not serve the best interests
5 of the veterans. I think that probably questions relat-
6 ing to specific units and when the herbicides were used,
7 you know, coming from the veterans groups it would be
8 fine. But I would be happy to hear any suggestions along
9 those lines.

10 The third question: "In reviewing our files on
11 Air Force personnel who were handlers of Agent Orange in
12 Vietnam, it appears that a significant proportion were on
13 TDY, temporary duty, during such exposure and hence may be
14 missed in the Air Force's proposed study of 1200 Ranch
15 Hands. Have you given any thought as to how such addi-
16 tional personnel might be identified and included in the
17 Ranch Hand study?"

18 I, of course, have not. I'm not directly in-
19 volved in the Ranch Hand study myself, although as a
20 member of the inter-agency work group and of the scien-
21 tific panel, we've been very interested, and so forth.
22 But I can't answer the question as to whether non-desig-
23 nated Ranch Handlers or other Air Force personnel who
24 might have been on temporary duty as Ranch Hands have been
25 identified.

1 Dr. Hobson, do you have something to add?

2 DR. HOBSON: At a meeting of the scientific
3 group, at which Dr. Shepard was not present for that part
4 of the discussion, the Air Force did go into this ques-
5 tion. They felt that it would not be possible to
6 identify those people through any records that are ex-
7 tant. Therefore, they felt that they could not expand it.
8 They looked rather desperately, as I understand, for a
9 way to expand the size of the Ranch Hand group in order to
10 make ^{this} study of greater significance. They have been unable
11 to do that.

12 Since that is quite a "clean" population where
13 there is a great deal known about them, to add people
14 where exposure is ^{suspected} but not known, would weaken the study.
15 So they have not been able to do it.

16 DR. SHEPARD: Any other questions or com-
17 ments?

18 MR. DeYOUNG: I'd like to come back to the
19 second question there. The herbs-tapes that were men-
20 tioned along with map print-outs and other information on
21 what we have been able to collect on troop movements at
22 least are available through the St. Louis office of the
23 task force.

24 DR. SHEPARD: Thank you.

25 MR. DeYOUNG: A couple of housekeeping items:

1 Is the transcript of the last meeting out yet?

2 DR. SHEPARD: It will be soon. I think it's
3 in its final phases of correction.

4 MR. DeYOUNG: Very good. Have any of the Commit-
5 tee members responded to the requests for evaluation or
6 review of the European studies that were dispersed at the
7 last meeting? Do you have anything in writing on that yet?

8 DR. SHEPARD: Yes, we have. What I'm hoping
9 to do is to collate those and send them around for a final
10 Committee -- well, what I will do is draft what I consider
11 to be a Committee consensus and then circulate those for
12 information and comment.

13 Thank you very much for attending the meeting and
14 we look forward to seeing you at the next one.

15 (Meeting adjourned at approximately 12:40 p.m.)

16 REPORTER'S CERTIFICATE

17 I hereby certify that the foregoing is a true and
18 accurate transcription of the proceedings of the meeting of
19 the Advisory Committee on Health-Related Effects of Herbi-
20 cides held at the Veterans Administration Central Office,
21 Washington, D.C., on Thursday, November 6, 1980.

22
23 
24 Doyne W. Spencer
25 Certified Shorthand Reporter

1 I hereby certify that the proceedings and evidence herein are contained
2 fully and accurately, as corrected.

3
4 

5 BARCLAY M. SHEPARD, M.D.
6 Chairman
7 VA Advisory Committee on
8 Health-Related Effects of Herbicides

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December 23, 1980

Advisory Committee on Health-Related Effects of Herbicides Transcript of Proceedings

(Seventh Meeting February 4, 1981)

1 VETERANS ADMINISTRATION
2 ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS OF HERBICIDES
3
4

5 Wednesday, February 4, 1981
6 Veterans Administration Central
7 Office
8 Room 119
9 810 Vermont Avenue, N.W.
10 Washington, D. C.

11 The Committee met, pursuant to notice, at 8:30
12 a.m., Barclay M. Shepard, M.D., Chairman, presiding.

13 ATTENDEES:

14 BARCLAY M. SHEPARD, M.D., Chairman
15 Veterans Administration

16 IRVING B. BRICK, M.D.
17 American Legion

18 RONALD W. DeYOUNG
19 National Veterans Task Force on Agent Orange

20 ADRIAN GROSS, Ph.D.
21 Environmental Protection Agency

22 LT. COL. RICHARD A. HODDER
23 Uniformed Services University of the
24 Health Services

25 NELSON IREY, M.D.
Armed Forces Institute of Pathology
for: Carolyn H. Lingeman, M.D.
National Cancer Institute and Armed Forces
Institute of Pathology

PHILIP C. KEARNEY, M.D.
Department of Agriculture

ALBERT C. KOLBYE, JR., M.D.
Food and Drug Administration

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ROBERT H. LENHAM
Disabled American Veterans

MARION MOSES, M.D.
Mount Sinai School of Medicine

SHELDON D. MURPHY, Ph.D.
University of Texas Medical School

RAYMOND R. SUSKIND, M.D.
University of Cincinnati College of Medicine

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P R O C E E D I N G S

(8:30 a.m.)

CALL TO ORDER AND OPENING REMARKS

DR. SHEPARD: Good morning, ladies and gentlemen. I think we best get started. We have a very full agenda this morning. It is indeed a pleasure for me to welcome you all to this quarterly meeting of the VA Advisory Committee on Health-Related Effects of Herbicides.

I think it is safe to say that this Committee has acted in a most responsible manner and has provided a tremendous amount of input to the Veterans Administration. It /has provided avenues of communication between the VA and other Federal and non-Federal agencies.

So, it is really a pleasure for me to host this meeting and to welcome you all to it.

We have with us, besides the members, a group of distinguished visitors. I am most pleased that these individuals have taken time from their busy schedules to be with us and share information in their particular areas of expertise.

We are most delighted to welcome Mr. Fredrick Mullen from the Veterans of Foreign Wars; Mr. James Striegel from JRB Associates; Dr. Giuseppe Reggiani from Switzerland; Dr. Clifford Roan and Mr. Harold Collins, who will bring us up to date on some very interesting work

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1 that has been done by the National Agricultural Aviation
2 Association, and we are particularly pleased to have our
3 friends from the Air Force, Major Al Young and Col. George
4 Lathrop.

5 I would just like to spend a few minutes bring-
6 ing you up to date on some highlights of activities being
7 undertaken by the VA, but before I do that, I would like
8 to introduce two new members of our Committee. First of
9 all, Dr. Marion Moses, who comes to us from Mount Sinai
10 Medical School and is in the Department of Environmental
11 Sciences. She works very closely with Dr. Selikoff
12 in the Environmental Sciences Laboratory.

13 Welcome to our Committee, Marion; it's nice
14 to have you here.

15 We also have Dr. Albert Kolbye, who comes to us
16 from the Food and Drug Administration and has had consider-
17 able experience with the issue we are addressing.

18 Dr. Kolbye, it is a real pleasure to have you
19 with us.

20 DR. KOLBYE: Thank you very much, sir.

21 DR. SHEPARD: We regret that a very faithful
22 member, Dr. Carolyn Lingeman from National Cancer Insti-
23 tute could not be with us, but she is ably represented
24 by Dr. Nelson Irey, who will have a word to say about
25 the status of the AFIP Agent Orange Registry.

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1 Dr. Nelson Irey, a long-time member of the
2 staff at AFIP, also has a distinguished career in the Army.
3 He is heading up the AFIP Registry so it is, indeed, a
4 pleasure to have you with us, sir.

5 We are very pleased to report some new develop-
6 ments since our last meeting. We have now awarded the
7 contract for the long awaited literature analysis. We
8 are delighted that JRB Associates was the successful
9 bidder. We will be hearing a little later on in the pro-
10 gram from Dr. Jim Striegel who is heading up that project
11 for JRB.

12 We have finally completed and distributed to
13 our field activities the videotape on Agent Orange, which
14 some of you have seen the previous editions.

15 As I say, the final edition is out and has
16 been distributed to all our medical centers, our regional
17 offices, our readjustment counseling centers, our informa-
18 tion service office area directors, and is currently
19 being shown to the veterans for whom it was intended.

20 We have issued our first copy of the Agent
21 Orange Bulletin and members of the Committee have it in
22 their packets, and we are working feverishly on getting
23 out the second edition.

24 The epidemiological study is, I hope, its last
25 stages of development as far as the contract award is.

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4. 1 concerned. Some of you may be aware of the fact that the
2 Government Accounting Office has been reviewing that
3 process and has made a report. We are now awaiting the
4 final decision from the courts as to our ability to
5 proceed with that important effort.

6 The Agent Orange Registry continues apace. We
7 now have well in excess of 40,000 veterans examined at
8 our various medical facilities and we have in excess of
9 20,000 of those individuals enrolled in the computer data
10 bank. So, we are now beginning to look at some of the
11 data that is in the data bank. We have already developed
12 procedures for analyzing and evaluating the informa-
13 tion that is in the registry.

14 We will be reporting on that at our next meeting
15 most likely.

16 I would now like to introduce Dr. Nelson Irey
17 who will just say a brief word about the status of the
18 AFIP Registry.

19 AFIP REGISTRY

20 DR. IREY: Thank you, Dr. Shepard.

21 The Armed Forces Institute of Pathology has
22 been designated as a center for collected of biopsy and
23 autopsy material on Vietnam veterans. We also have been
24 designated as a center for a similar purpose by the Surgeons
25 General of the Army, Navy and Air Force. We also

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1 received a certain amount of material from civilian
2 hospitals and pathologists unrelated to the Government
3 agencies..

4 The majority of our material, however, is coming
5 from the VA medical network. So far, we have about 170
6 cases.

We are trying to find
7 out what the medical problems of the Vietnam veterans
8 are currently as reflected in biopsy and autopsy material.
9 160 or 170 cases is a rather small number, but they are
10 beginning to come in in much greater numbers in the last
11 three or four months.

12 We are looking for trends, peaks either in
13 anatomic sites, or in diagnoses. So far, having
14 analyzed in a preliminary fashion the data of these
15 roughly 170 cases, we have found no peaks, no trends in
16 either of these major areas.

17 Dr. Lingeman, who is the regular member here,
18 who I am representing today

19 is conducting a case control study on soft
20 tissue sarcomas in conjunction with, in cooperation with
21 Dr. Franz Ensinger of the AFIP, who is in charge of the
22 soft tissue department, and that is in its incipient
23 stage and has nothing yet to report through her.

24 Thank you very much, Dr. Shepard.

25 DR. SHEPARD: Thank you very much, Nelson.

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A couple more housekeeping notes that I should have mentioned earlier. First of all, we are happy to announce that Dr. Patricia Honchar, from the National Institute of Occupational Safety and Health has been appointed a regular member of the Committee. She has attended Committee/^{meetings} as an alternate on a number of occasions.

The person for whom she was an alternate, Mr. Richard Lemen, because of press of other duties has resigned from the Committee. Dr. Honchar has very graciously accepted the appointment in his place.

She was to have been here to report on the Dioxin Registry on which she has been working so diligently. Unfortunately, something came up at the last minute which prevented her from being here, so she sends her apologies. She will be preparing a report in the not too distant future as to the status of the Dioxin Registry, and we will circulate that to the members of the Committee for their information and consideration.

For those of you who have not registered, we would like to keep a record of visitors and guests, so please be sure that you sign in at the back of the room, if you have not already done so.

As in past meetings, we will make a portion of the program available for questions to the members of the

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1 Committee.

2 In the event that any of you have questions for
3 members of the Committee please indicate

4 this to Don Rosenblum, who is in the back of the room.

5 He has cards on which to write questions. At
6 the end of the formal agenda, we will open up the floor
7 for questions to members of the Committee.

8 One of the strengths of this Committee, I feel,
9 is the representation and the participation of our dedica-
10 ted service organizations and we are most pleased to have
11 their participation.

12 I would now like to call on Dr. Irving Brick,
13 who represents the American Legion and ask him what is
14 new in the Legion that would be of interest to our
15 Committee.

16 REPORTS FROM VETERANS SERVICE ORGANIZATIONS

17 DR. BRICK: Good morning.

18 The Legion continues to be bombarded with
19 requests relative to when the Committee's work is going
20 to be done and / ^{what} is going to come out of this Committee's
21 work. The level of interest in the Agent Orange issue
22 seems to have peaked a bit. I don't think that it is
23 as intense as it was, but there is still a lot of interest
24 in it.

25 The American Legion is conducting with its

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8.

1 service officers in the field a questionnaire of veterans
2 relative to how this problem is being handled in the in-
3 dividual medical centers.

4 I think the preliminary data would indicate that
5 there's a wide variance relative to the knowledge that
6 many of the medical centers have, and I am sure that
7 Central Office is attempting to, by various publications
8 such as the bulletins which go out, such as the Agent
9 Orange Bulletin and the Vanguard, to disseminate current
10 information relative to the problem.

11 In rating, my participation has a lot to do with
12 cases before the Board of Veterans Appeals and we are not
13 seeing many cases. We're not seeing a host of cases, but
14 we are seeing sporadic cases which come to our attention
15 and usually -- as a case I handled just yesterday, a 34-
16 year old veteran with cancer of the bladder whose urologist
17 claims that this is related to his exposure to Agent
18 Orange.

19 In order to give the veteran a shake at some
20 kind of medical opinion, when he gets an opinion such as
21 this from his own physician, who is a certified specialist
22 in urology in this particular instance, I am hopeful that
23 your office, Dr. Shepard, in Central Office will be of
24 assistance to the Board of Veterans Appeals, if you are
25 requested to give opinions on matters such as this.

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1 I think the set up that was established with you
2 as the Chief and the Special Assistant for Environmental
3 Medicine will serve a useful purpose when rating boards
4 avail themselves of this expertise in your office, and I
5 trust that this is going to be helpful in these matters.

6 Members of this Committee should understand
7 as far as veterans are concerned, the bottom line is compen-
8 sation. I know that is difficult for some of the members
9 of this Committee to understand, but particularly when
10 economic situations is as stringent as it is and the budget
11 is going to be stringent, we are told repeatedly on TV and
12 papers and from the White House, that I think we are going
13 to be faced, service offices in the field and people who
14 work with veterans organizations here in Washington are
15 going to be faced with many, many more claims of this sort.

16 I think that the Veterans Administration should
17 gear up to handle these claims in a sympathetic and as
18 fair a manner as possible with the limited knowledge
19 that we have at the present time relative to the Agent
20 Orange problem, and its causation of various alleged
21 diseases.

22 Thank you.

23 DR. SHEPARD: Thank you very much, Dr. Brick.

24 I appreciate your comments about the role our
25 office should play relating to the Board of Veterans

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1 Appeals. It is perhaps not coincidental that just yester-
2 day, or was it Monday; I guess it was Monday, we were
3 privileged to give a briefing to some key members of the
4 Board of Veterans Appeals, informing them as to
5 the agency 's ongoing activities
6 and plans for the future, and, also, encour-
7 aging a closer relationship, a closer dialogue with that
8 most important effort of the Veterans Administration.
9 In fact, we have now ^{been} referred a case for our
10 contributions, in terms of helping ^{make} some diffi-
11 cult decisions. I certainly share your concern that
12 there is still, and I suspect there always will be, a
13 lack of understanding in the medical community on this
14 complex problem.

15 It is unfortunate that individuals are persuaded
16 to make comments such as you have indicated. I think
17 with a physician making the comment that an individual's
18 bladder cancer was likely caused ^{by} his exposure to Agent
19 Orange which is not fully supported by the scientific
20 data, just serves to further raise the concern of
21 veterans quite apart from the compensation issue. This is
22 also very important, of course, but ^{when} comments or information
23 such as that are widespread, obviously, you are going to
24 raise concerns. And so, I think, that this Committee can
25 serve a very useful function in trying to sort out the

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1 facts and put these things in perspective.

2 I'd like next to call on Mr. Robert Lenham for
3 his comments.

4 MR. LENHAM: Thank you.

5 I share similar views with Dr. Brick. We
6 continue to see throughout our offices, veterans coming
7 in and we are experiencing frustration on the national
8 service officers' part in as much as we really don't
9 have anything that we can conclusively reiterate to the
10 veteran with respect to the issue.

11 Doubly so, the veteran is frustrated when he
12 files a claim and basically is going through the motions,
13 so to speak, and also when he goes to the VA hospitals
14 and has medical examinations.

15 Some of the inquiries that we have seen from the
16 veterans come from the medical examinations and they feel
17 evidently going in that they will be able to get some type
18 of a result or some type of a comment from the examining
19 physician of, you know, whether or not they have in fact
20 dioxin in their system, and some type of a positive or
21 negative answer either way that would guide them. And
22 they don't have any feedback from the physicians. That adds
23 fuel to the fire in the frustration level.

24 It is one that all of us are dealing with. We
25 have no other choice right now until we can get some

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1 conclusive studies that will provide us with the guidelines
2 on which to go. And I think for the better part, that the
3 national service officers out in the field, you know, have
4 handled themselves quite well. But you can see where some
5 frustration comes because they have to deal with these
6 veterans daily, and don't really have anything to offer
7 them.

8 We have gotten over probably 2,000 inquiries
9 now directly into our headquarters, and more so out in
10 the field, so the interest and the concern is still there.
11 And will still be there, I think, until this Committee
12 comes out with some conclusive evidence.

13 DR. SHEPARD: Thank you.

14 I appreciate it.

15 Yes, sir.

16 DR. GROSS: I have two questions on this.

17 Number one, what has been the impact of this little
18 orange bulletin that was issued whose purpose was to allay
19 fears, such as you speak of the need for gathering informa-
20 tion. That's question number one.

21 Question number two: what are the service
22 organizations themselves doing to explain the workings of
23 the Committee, the area -- the stage at which the science
24 is here. We're waiting for lots of things; we really don't
25 know. What are you folks doing to put certain minds at

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1 rest?

2 MR. LENHAM: Okay. On your first question with
3 regards to the VA's pamphlet on Agent Orange, we have
4 gotten comments back that it is superficial. It is some-
5 thing that is trying to relieve concerns, but it is not
6 working. Now, this is comments from the veterans.

7 The answer to your second question with respect
8 to the organization, our organization has a monthly maga-
9 zine which goes out to over -- well, over 700,000 individ-
10 uals. We periodically put updates in that magazine with
11 respect to what this Committee is doing and what other
12 research is coming in with respect to the issue of Agent
13 Orange so that we can apprise our members of where we are
14 right now.

15 And then the national service officers in there
16 own areas conduct what we call open meetings where they
17 go out and speak to the veteran populations, to our
18 chapter members and apprise them of where we are right
19 now with this issue.

20 That is the efforts that our organization, the
21 DAV has taken.

22 DR. GROSS: Do you feel you are being effective
23 with these things?

24 MR. LENHAM: Well, effective as much as we can
25 be with what we have to work with. We are keeping them

1 apprised out in the field with as much knowledge as we
2 are obtaining here.

3 DR. SHEPARD: Thank you very much, Bob. I
4 appreciate your comments. I think that in the press of
5 all of our other activities, we have perhaps not

6 maintained as close liaison with service organiza-
7 tions here in Washington as we could have in this particu-
8 lar issue. The thought occurs to me that it might be
9 helpful for us to perhaps provide, on a regular basis,
10 some material that you could include, in your own judgment,
11 in your various publications, and use that avenue to, at
12 least, inform veterans as to what the VA is doing.

13 MR. LENHAM: We would welcome that.

14 DR. SHEPARD: Good. In the matter of the follow-
15 up, and I should have mentioned that earlier, many of you
16 know that we conducted a rather small survey.

17 A questionnaire was mailed to approximately
18 100 randomly selectly veterans in seven of our medical
19 centers to get some kind of a feel as to their impressions
20 of the Agent Orange exam experience.

21 It came back -- we were gratified that we got
22 over 55 percent response from that questionnaire, which is
23 I think, a pretty good average when you consider
24 responses to questionnaires in general. We tried to keep
25 it simple and easy to answer.

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1 One of the things that came through from that
2 was that we havenot done as well as we should have in terms
3 of insisting that follow-up information be provided to
4 veterans following their examination.

5 In a number of instances, I think, what has
6 probably gone on is that the veteran has been told that
7 if you don't hear from us that means everything is okay.

8 We don't feel that is totally satisfactory in an
9 issue that raises as many concerns as this has. Conse-
10 quently, we have just recently gone out with a circular
11 to all our medical facilities giving some very specific
12 guidance as to how the veteran will be informed as to the
13 results of his physical examination, the laboratory data.
14 Whether the results were negative or positive, they
15 will be given a formal notification and will be counseled
16 at the conclusion of the physical examination as to the
17 physical findings. So, we are hopefully closing that gap.

18 We are in hopes that as time goes on, veterans
19 will feel that they are getting better follow-up informa-
20 tion.

21 Thank you, Bob,

22 I would next like to call on Mr. Fredrick Mullen,
23 Veterans of Foreign Wars.

24 Is Mr. Mullen here?

25 MR. MULLEN: I think that just about all veteran

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1 service organizations are experiencing the same difficulties
2 as pointed out by both Dr. Brick and Mr. Lenham.

3 Both the service organization representatives
4 and the veterans are up against a "no-win" situation at
5 this point. There is nothing we can do in representing
6 these veterans to allay their fears and to assure them
7 that everything possible is being done.

8 What we do experience is a lot more questions
9 regarding heavy metal exposure. We don't believe enough
10 study has been done in this area.

11 There was approximately 3 1/2 million pounds of
12 heavy metals disseminated in Vietnam. And when you
13 consider that 5 milligrams constitutes a toxic dose, then
14 we believe that there is reason for concern in this area.

15 The Veterans of Foreign Wars would like to see
16 more done in this area of screening by the Administration
17 such as nail and hair samples and a possible patch test
18 in the cases of skin diseases.

19 Just about the only skin disease at this point
20 that is being related to exposure of any type is chloracne.
21 And when you consider that the different skin diseases
22 caused by exposure to arsenic are protean, then, again,
23 we believe a lot more cases can be allowed based on
24 arsenic exposure alone.

25 Again, we are up against a "no-win" situation at

1 this time and we would like to see more done and a little
2 bit more speed put into the study that is being conducted
3 at this point.

4 Thank you.

5 DR. SHEPARD: Okay. Thank you very much for
6 sharing that with us, Fred.

7 As I say, again, I hope that as time goes on
8 we can keep the lines of communication very clearly open.

9 If you have concerns in areas in which you feel
10 that the Committee should consider, then I hope you will
11 free to bring them to our attention.

12 MR. MULLEN: Thank you very much, Dr. Shepard.

13 Yes, Dr. Murphy?

14 DR. MURPHY: Mr. Mullen, when you mentioned
15 heavy metals, are you referring to the arsenic containing
16 herbicides?

17 MR. MULLEN: Specifically arsenic, the inorganic
18 compounds.

19 DR. MURPHY: The inorganic?

20 MR. MULLEN: Yes, sir.

21 Trivalent and Pentavalent.

22 DR. MOSES: That's organic.

23 MR. MULLEN: Excuse me, organic.

24 DR. KEARNEY: Excuse me. I think what we are
25 talking about is MSMA.

1 DR. MURPHY: Could you say what that is, Phil?

2 DR. KEARNEY: It's the monosodium salt of
3 methane arsenic acid. I guess we would really call it
4 an organic form. It is the plus five form, but I under-
5 stand what you are saying.

6 MR. MULLEN: I understand that the inorganic
7 arsenic would be, I believe, more toxic --

8 DR. KEARNEY: Yes.

9 MR. MULLEN: -- but once this organic chemical
10 gets into the soil and the acid and the soil combines, I
11 believe that there is potential to decompose into an in-
12 organic state.

13 DR. KEARNEY: That's correct.

14 MR. MULLEN: And this would be carried in the
15 streams, in the marshes and we have experienced a lot of
16 complaints specifically regarding skin diseases of the
17 feet which are almost more often than not diagnosed as
18 unknown etiology, and we believe that if patch testing is
19 done on people who still have these skin conditions -- if
20 patch testing is done, there may be a correlation between
21 the arsenic exposure and the specific skin diseases that
22 these veterans are experiencing at this point.

23 DR. KEARNEY: Very good.

24 MR. MULLEN: Yes, sir?

25 DR. SUSKIND: Mr. Mullen, I'm wondering whether

1 you are aware of the intensive studies that were carried
2 out through the Armed Forces of the problems of the feet of
3 combat troops in Vietnam. These studies were carried out
4 by the University of Miami group, headed up by Dr. Harvey
5 Blank, and I believe that the studies have been published.

6 The problem was generally known as immersion foot.

7 MR. MULLEN: Yes, sir, I am well aware of that.
8 That's been a problem in all three wars.

9 DR. SUSKIND: And many of the veterans had
10 sequelae as a result of that problem and I am just wonder-
11 ing whether that was also being considered as a possibility
12 rather than the cacodylic, or whatever the cadodylic
13 was?

14 MR. MULLEN: Well, we're not disputing the fact
15 that a lot of these cases of skin disease are caused
16 specifically by immersion foot or by fungal infections, but
17 we believe that if there is positive patch testing and a
18 skin condition arises, which is almost identical to the
19 skin condition which this veteran has, then surely that
20 raises reasonable doubt as to the etiological agent, or
21 factor which caused the problem.

22 Again, we are not specifically limiting our
23 complaints regarding arsenic exposure to skin conditions.
24 A lot of these complaints from veterans involved the
25 gastrointestinal system and the central nervous system,

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1 and, more specifically, peripheral neuropathies and GI
2 bleeds, and dysentery-type states. And I believe it is more
3 than circumstantial or coincidental that the presenting
4 symptoms that we find in these service medical records are
5 almost identical to the presenting systems that one would
6 find in cases of minimal arsenic exposure, or cases of a
7 toxic level, 5 milligrams or more.

8 So, we are not specifically limiting this to a
9 foot condition, or a skin condition, but rather we would
10 like to give the Veterans Administration a tool by which
11 to allow a lot more of these claims because, as Mr. Lenham
12 says, the bottom line is compensation, and that is our sole
13 purpose to see that these veterans get what is coming to
14 them.

15 At this point the Veterans Administration tells
16 us: we don't have any way, the scientific community
17 doesn't give us anything to go on. There is no correlation
18 between dioxin exposure and disease.

19 Now, the VA has also come out with a directive
20 stating that if you were in Vietnam and you claim exposure,
21 we will concede exposure unless you were a desk jockey.
22 Well, this does nothing for the veteran because he still
23 goes in there and he is told "no." Okay, you've got
24 exposure. Now, prove what you have got is caused by that
25 exposure. Well, he can't, and we believe that by more

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1 study into this heavy metal problem, that they may have
2 means by which to allow some of these cases.

3 DR. SUSKIND: Thank you.

4 DR. KEARNEY: Mr. Chairman, just one point of
5 clarification.

6 Dr. Suskind is right, it is cacodylic acid rather
7 than -- it is a derivative of it.

8 MR. DeYOUNG: This is not the first time that I
9 have heard the expression of concern about the Agent Blue
10 that was used.

11 To that same end, a researcher in Chicago about
12 two years ago started taking samples of hair and nails
13 from certain Vietnam vets in a pilot study. I do not know
14 what the results of that study are, but I guarantee I
15 will find out for you.

16 MR. MULLEN: I believe there were 17 positive
17 samples found, and I think it was Dr. Bederka, if I am
18 not mistaken.

19 MR. DeYOUNG: It was, and that number strikes me
20 as familiar, too, but I'll make sure of it.

21 MR. MULLEN: Yes- Nothing more has been done
22 since that point that I know of.

23 DR. SUSKIND: When you talking about the examina-
24 tion of hair and nails it is important to consider how long
25 after the exposure these samples were taken. If it were

1 10 years after the exposure, you wouldn't expect to
2 find it in hair and nails. If it were two months after
3 the exposure, you still would because the presence really
4 depends upon the growth of the hair and the nails. And
5 there are time limits to finding arsenic or any other
6 heavy metal for that matter in hair and nails depending
7 upon the rate of growth for the hair and nails.

8 MR. MULLEN: Well, from what I understand, it
9 can take as long as 10 years in some cases for this to
10 be excreted in certain individuals. Now, it is subject to
11 different idiosyncrasies in individuals, but there is
12 also some -- through some research I've done, I have found
13 that there is potential for storing arsenic in the liver
14 and kidneys.

15 Again, we are talking about the service medical
16 records. We are looking at the findings of the presenting
17 symptoms that we are seeing there. Alopecia and skin
18 conditions, gastrointestinal symptoms, and I believe if
19 you find this set of symptoms and this veteran has any
20 residual whatsoever from that particular problem, that it
21 should be service connected because there is certainly
22 reasonable doubt there.

23 DR. MOSES: One of the things that
24 has to be considered in arsenic is seafood. It
25 happens to be fairly high. If you want to do your study,

1 you might want to consider whether they live on a coast
2 or not. Although you are right about it can take a long
3 time, that is assuming that there are added continuing
4 exposures.

5 MR. MULLEN: Well, we are talking about in most
6 cases, these people were in the field sometimes in excess
7 of a year.

8 DR. MOSES: No. I mean, since 1969 or '70
9 when they came back.

10 MR. MULLEN: Oh, I see.

11 DR. MOSES: You would have to assume that for
12 10 years nobody had any exposure to arsenic and we're all
13 exposed to arsenic, anybody who eats fish is certainly.

14 In fact, when you want to do a urinary evaluation
15 for arsenic, we always ask people to stay away from sea-
16 food for at least three days because we don't feel that
17 we can get an accurate measure.

18 The other point with hair and nails, you're
19 right, it is important, but it is extraordinarily difficult
20 to sort it out. I'm not saying you shouldn't do it. We
21 should try to do all things that we can to get any
22 biological indicators we can, but you may find yourself
23 in a situation that you have got numbers, letters, values
24 that you just don't really know what they mean because
25 of contamination of other sources. But I think it is

1 a good point and needs to be addressed absolutely.

2 DR. SHEPARD: Dr. Kolbye?

3 DR. KOLBYE: Just so those remarks are not mis-
4 interpreted as indicating that our fish supply is poison,
5 I'd like to point out that those arsenicals are in the
6 organic form and very readily and quickly excreted from
7 the body and pose no public health risk.

8 (Laughter.)

9 DR. MOSES: I'm sorry if I offended anybody
10 today.

11 DR. SHEPARD: I failed to indicate that Dr.
12 Kolbye is Associate Director of the Bureau of Foods for
13 the FDA and so his point is well taken.

14 (Laughter.)

15 DR. SHEPARD: Many of you are aware, I'm sure
16 of interest directed towards other ecosystems, including
17 the fish life in the Great Lakes, which has received some
18 recent attention.

19 Dr. Kolbye and I attended a meeting at the State
20 Department a while back at which this issue was raised so
21 that obviously there are many other agencies that are
22 interested and working hard on this very complex issue
23 of potentially toxic substances in the environment.

24 MR. MULLEN: Thank you very much, I appreciate
25 it.

1 DR. SHEPARD: Let's move along now to the next
2 portion of our agenda, and we are very fortunate to have
3 Jim Striegel here who will tell us a little bit about
4 JRB's efforts to enlighten us all and bring together a
5 vast quantity of literature and sort it out for us.

6 LITERATURE ANALYSIS REPORT

7 DR. STRIEGEL: Let me first say that I am pleased
8 to participate in this effort.

9 As a bit of history, about a year ago the
10 Congress passed Public Law 96-151, which required the
11 Veterans Administration to conduct a couple of studies,
12 one of which was a review of the worldwide literature on
13 herbicides used in Vietnam.

14 JRB submitted a proposal in the middle of the
15 year and were awarded a contract for nine months just
16 before Christmas.

17 To introduce ourselves, JRB is a part of Science
18 Applications, Inc., which is a high technology research
19 company with offices in 70 cities around the country and
20 about 4,000 scientists on the staff.

21 Our work is primarily in environment, energy
22 and health.

23 We recognized immediately that a great deal
24 of work has already been done on reviewing
25 this literature. We would solicit your assistance in

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1 consolidating this material one more time in one more pile
2 to be gone through by a group of scientists.

3 We have already met with Dr. John Moore of the
to Study the Possible Long-term Health Effects of Phenoxo Herbicides and Con-
4 Interagency Work Group. We are contacting several of the tam-
5 people on this panel and other researchers in the Federal inants
6 Government who have been working on the problem of
7 herbicide exposures in Vietnam. We have obtained the
8 assistance of scientists like Dr. Abraham Lilienfeld of The
University;
9 Johns Hopkins/ Dr Steven Safe at Guelph University, who
10 is working on the Canadian study of TCDD; and Dr. Walter
and
11 Melvin at Colorado State University; / other people who
12 have been working on this project, in essence, since the
13 issue arose 10 years ago.

14 I would like now, just briefly, to discuss the
15 nature of the project. As I said, it is once more to
16 collect and gather and review in one place the published
17 literature on all of the herbicides used in Vietnam, which
compounds.
18 includes about 15/ The major concern, of course, is
19 with the phenoxo herbicides.

20 We are right now going through the process of
21 contacting people who have been collecting that literature
22 and have researched it. We have established in our firm
23 a system for tracking the literature as it comes in and
24 making sure it gets assigned to the correct scientist for
25 review.

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We are
 1 now in the process of collecting literature. We
 2 have access to everything that the Veterans Administration
 3 itself has on hand. We also have access to the Environ-
 4 mental Protection Agency's files on both the suspension
 5 hearing and the cancellation hearing for 2,4,5-T,
 6 which amounts to something on the order of 3,500 documents.
 7 are documents
 8 A great many of these/legal/ having to do with the hearings
 9 the
 10 rather than/scientific literature, but we have access to
 11 all of
 12 / them. And we would like to be guided to other sources
 13 of information as we gather this material.

11 We will begin very shortly to conduct update
 12 searches on more recent literature that has been published
 13 since the EPA hearings, and beyond

14 what is on hand at the Veterans Administration.

15 The literature will be reviewed and annotated,
 16 roughly beginning in February, for its validity, for the
 17 findings and the validity of those findings, for
 18 the nature
 19 of the studies described.

19 Our staff includes toxicologists, epidemiologists,
 20 pharmacologists, chemists, plant physiologists, geneticists,
 21 occupational medicine physicians.

22 We will, by mid-March present to the Veterans
 23 Administration a draft bibliography, simply a listing of
 24 the articles that we have found to fit our relevancy
 25 criteria for the nature of the study we're conducting, and

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1 to be the articles that we will continue to review and
2 annotate in depth.

3 Later in the year, as the
4 material is compiled into categories and specific issues,
5 problem areas, or information gaps are identified, the
6 material will be passed through a senior science review
7 of both in-house scientists and consultants like Dr.
8 Lilienfeld and Dr. Safe, and others. And by mid-September,
9 we will produce the report.

10 We currently envision the report to be in two
11 volumes. The first volume will be the narrative discussion:
12 a brief overview of the use of herbicides in Vietnam;
13 a discussion of the published literature on the botanic
14 effects, environmental transport and fate, the nature of
15 exposures, issues such as species variability; and we hope
16 to compile a good summary of all of the industrial accidents
17 as well that have taken place.

18 Then a chapter that will address, in fact, the
19 human health effects, emphasizing long-term chronic and
20 delayed toxicity, potential for mutagenicity, teratogenicity,
21 carcinogenicity, as addressed in the literature.

22 a chapter on
23 And then the findings of the literature review itself,
24 which will include the conclusions of the literature, the assessment
25 of the science contained in the literature, and particular
attention to the limitations and gaps in information that

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1 currently exist.

2 The second volume of this report would be, in
3 fact, the annotated bibliography of all the literature
4 that was reviewed, which might be quite extensive. We
5 also hope to include in the report / ^{an appendix} to address current
6 protocols that are being developed for epidemiological
7 studies and some prospective work. All literature reviews
8 must stop at some date if you are going to publish a report.

9 We would like to try at least ^{to} keep our attention
10 to studies that we know are coming into the literature
11 that have been identified for us. We would try to address
12 these in some kind of an appendix as well.

13 We will try to get to -- our objective is to
14 get to all of the literature, all of the scientific litera-
15 ture that exists in the published domain. And we hope that
16 you, those who have been working on this project for the
17 past many months and years, can help guide us and help us
18 get to those resources so that our efforts can be devoted
19 to the science assessment rather than to what can be a very
20 expensive process of ^{identification and} acquisition.

21 DR. SHEPARD: Thank you very much, Jim.

22 Are there any questions from members of the
23 Committee?

24 Dr. Murphy?

25 DR. MURPHY: Will your literature review cover

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1 herbicides in the broad sense, or will it be focused on
2 Agent Orange and the constituents and contaminants thereof?

3 DR.. STRIEGEL: The terms of the project are to
4 address all herbicide use in Vietnam, about 15 Many
5 of these were used only ^{on/an} experimental basis and there
6 will be very little published literature on many of them.
7 So, by the structure of the published literature, we will
8 be directed to where the problem has been perceived to be,
9 which is, of course, TCDD and the phenoxy herbicides primarily,
10 and other herbicides that have been raised in the published
11 literature.

12 DR. KEARNEY: Just a suggestion. I noticed you
13 said, "botanical effects." I wouldn't get bogged down
14 in this. We were asked recently to supply some information.
15 I think the Department forwarded 15 pounds of literature.
16 I think the veterans and this Committee would be better
17 served if we looked into more the health related aspects
18 (i.e., botanical effects)
19 of the thing because that/is a maze that you can get into
20 and never get out of.

20 DR. SHEPARD: Dr. Suskind?

21 DR. SUSKIND: I'm just wondering whether or not
22 this is to be a critical review of the literature or just
23 a review of all entries that are found? A critical
24 review of the literature would, of course, be much more
25 useful to scientists, whether they were conducting

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1 epidemiological studies or conducting laboratory studies.

2 DR. STRIEGEL: The intent is certainly to do
3 a critical review to assess the nature of the study reported
4 in the literature; to make our assessment, our science
5 assessment of the validity of the population used, or the
6 of the structure/methodology used, and to assess the findings that
7 were reported and to make some kind of judgment on our
8 valuation of those findings.

9 DR. SUSKIND: Are you going to use consultants
10 for such a critical review? I would imagine that JRB
11 doesn't have all of the disciplines which would be
12 necessary to do a thorough comprehensive review.

13 DR. STRIEGEL: As a matter of fact, the answer
14 to that is, yes, on both counts. JRB and our parent
15 corporation, Science Applications, Inc., covers virtually
16 all of the scientific areas required. However, we also
17 have on our staff consultants whom we have proposed and
18 who have agreed to work on this project. we will use So, both
19 senior scientists reviews from in-house and from consul-
20 tants.

21 DR. KOLBYE: May I just inquire. Is this going
22 to be what I would call in my own language, an unfocused
23 review, or are you going to pose several critical questions
24 and direct your attention to those questions with emphasis
25 during the course of your review?

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1 DR. STRIEGEL: In the opening stages of the pro-
2 ject it is unfocused, in the sense that we are gathering
3 everything we can get. Then to review it and find where,
4 ultimately, where it will focus on issue areas that are
5 identified in the literature. But the initial attempt
6 is to throw the net as widely as possible.

7 DR. KOLBYE: The reason I'm thinking about
8 this is that one of the issues is with respect to the TCDD.
9 It deals with its mechanism of toxicity with reference to
10 the induction or influencing the incidence of cancer. And
11 it would be of great interest, I think to look at liver
12 toxicity in an animal study, the various animal studies,
13 and perhaps specifically to review some of the histopath-
14 ology from some of those studies if we have dose-response
15 data.

16 And a literature review per se might not get at
17 some of the more critical questions that deal with a
18 hyperplastic toxicity, for example.

19 DR. BRICK: Who is this contract with, VA?

20 DR. STRIEGEL: Yes, the Veterans Administration
21 is the funding agency.

22 DR. BRICK: Well, this is a point that I would
23 like to address. If you are going to do a thorough
24 review of the literature, as it was pointed out, and
25 good, we say, you are going into botanical, I don't want

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1 to use a dirty word, but Dr. Kearney kindly points out
2 correctly, you'll get lost in a bog and a morass.

3 Now, this Committee is interested in the health
4 effects as they pertain to human beings and I think if
5 you cut away all this malarkey about the scientific stuff
6 in plants, the environment, et cetera," and focus only
7 health related problems, if this is what's not going to
8 be done in your program, this is a waste of money. It is
9 a waste of money completely.

10 I'd like to know what the terms of the VA
11 to this project are? What are the terms?

12 DR. SHEPARD: We can certainly provide you
13 the RFP, Dr. Brick.

14 Let me just say in defense of Jim, and I was
15 involved in some of the early discussions, I think that
16 the botanical aspects are simply -- correct me if this
17 isn't your understanding, Jim -- but I think that we just
18 needed a short part of the review to indicate what are
19 some of the basic mechanisms in plants -- on which
20 herbicides work. In other words, how do herbicides work?
21 Not a long discussion of the pros and cons, the detailed
22 minutia of photosynthesis and the effect of herbicides
23 on them. Not at all. So, please don't get the impression
24 that we have a built-in danger that we are going to
25 get bogged down with botanical morass. It is, of course,

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1 our primary concern to review the biological aspects of
2 this substance and not the botanical.

3 Yes?

4 DR. MOSES: I would like to ask Al Young,
5 hasn't that already been done by the Air Force?

6 MAJ. YOUNG: Well, we just recently published
7 a book on 2,4,5-T and the botanical aspects were very
8 heavily covered. The only reason it's important, of
9 course, is because much of the material in Vietnam was
10 applied to foilage. If it is rapidly absorbed, that means
11 there is less in terms of exposure. This emphasis ought to
12 be brought out.

13 If it isn't absorbed and it is on the surface,
14 then you see exposure would be much greater. So, those
15 kinds of mechanisms ought to be brought out as it influences
16 exposure. But as to the mechanism of how these things
17 work, there are 20,000 articles of efficacy ^{that} do not
18 need to be looked at. We've already finished that
19 study & published it.

20 DR. BRICK: Good. You better give it to him.

21 (Laughter.)

22 DR. SHEPARD: That would be most appropriate and
23 perhaps I'm not remiss for having already done that. But
24 we are still in the relatively early stages of this project,
25 and I think it would be a good idea, Jim, if we could

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1 circulate to members of the community our next status
2 report so that they would be apprised of where we are.

3 DR. STRIEGEL: Certainly.

4 DR. SHEPARD: And also solicit their comments,
5 and we would like to keep them abreast of the progress .
6 And please, members of the Committee feel free to give
7 Jim or myself any input that you think is appropriate.

8 DR. STRIEGEL: Yes, do.

9 DR. SHEPARD: Dr. Suskind?

10 DR. SUSKIND: I'm sure Dr. Striegel knows that
11 there have been many literature reviews of phenoxy
12 herbicide.

13 DR. STRIEGEL: Yes.

14 DR. SUSKIND: And some of us actually felt
15 that, oh, here is another one. I don't know whether that
16 comment really has any merit any more. Certainly it
17 isn't appropriate. But, what I would suggest is that
18 you and JRB determine where those other literature surveys
19 are so that you could have access to them.

20 DR. STRIEGEL: I think we have several in-house
21 already.

22 DR. SUSKIND: Well, there may be many others
23 that are actually related to on-going research work and
24 they are not published.

25 DR. STRIEGEL: Yes.

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1 DR. SUSKIND: I can name four or five centers
2 of phenoxy herbicide research which must have literature
3 surveys in order to function. And so I think that if you
4 were aware of that, and this is not just Federal agency
5 activity, I am talking about university activity.

6 DR. STRIEGEL: Yes

7 DR. SUSKIND: That it would be helpful to you
8 and it might even shorten or decrease the work load. Nine
9 months is not a long period of time to do this. So, I
10 think JRB is going to need all the help they can possibly
11 get.

12 DR. STRIEGEL: Thank you. I agree entirely.

13 DR. SHEPARD: Do you have a comment?

14 DR. MURPHY: I think maybe Dr. Suskind answered
15 my question because, when we were naming months, September
16 was sort of a key one. I wonder if that was this
17 year or --

18 DR. STRIEGEL: Yes, this year.

19 DR. MURPHY: -- because I would agree with Dr.
20 Brick's comment to the extent that you do have -- I think
21 for this particular effort, at least, it should be focused
22 toward human health effects. On the other hand, I think
23 one shouldn't denigrate mechanism studies in the sense of
24 basic research that leads to an understanding of potential
25 for human health effects. And there has been some very

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1 interesting and perhaps meaningful research done in that
2 area with cellular reactions and so forth, but I think
3 it needs to be taken into consideration. I can't imagine
4 how you are going to be able to do this by September
5 unless you do as --- approach it by a fairly specific
6 question and really zero on that. And I would think
7 you would want to use your own staff and consultants in
8 a very directed manner.

9 is it
DR. STRIEGEL: Yes, that / exactly, and part of
10 the reason I'm here today.

11 DR. KEARNEY: For example, Mr. Chairman, there
12 is -- the National Academy Science spent two years putting
13 together a rather large arsenic report which covers many
14 of the subjects which we discussed earlier here today, the
15 chemistry of arsenic in soils, the health effects, the
16 sources. That would be useful to you.

17 DR. SHEPARD: And, please, if any of the members
18 of the Committee have any knowledge of similar efforts that
19 have been done, please share them with us, because this will
20 be very helpful, as Dr. Murphy has so appropriately pointed
21 out, the time left for the accomplishment of this effort
22 is short indeed.

23 DR. MOSES: I don't understand the terms of
24 this contract. What if it does turn out that nine months
25 just really isn't going to bring forth this child? Then

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1 what happens? Is there something in the contract to extend
2 this or do you just say, this is what we have and here it
3 is, or -- Because this could be very important. It seems to
4 me if you find that you are overwhelmed and can't meet
5 this deadline, what has been arranged for that?

6 DR. SHEPARD: Well, I'm not an expert in contract
7 negotiations, but I would hope that there would be
8 a safety clause or something that would allow JRB to
9 appeal for some more time.

10 DR. BRICK: Dr. Moses, may I address that point?

11 DR. MOSES: Yes.

12 DR. BRICK: There is a publication in this town
13 called, Washington Monthly. It's a very delightful
14 publication in which a current issue -- a couple of months
15 ago -- talked about Government consultants and Government
16 contracts and the ploys that are used with reference to
17 a contract being written for September, let's say, as in
18 this case, and that's part of the ploymanship of the
19 contractors, because they never get finished by the
20 appointed date, and they always go for an extension.
21 And I don't know the dollars here, the numbers of dollars
22 we're talking about, but they are probably considerable.
23 And if you want to know how this works, I would recommend
24 this article in the Washington Monthly to you.

25 (Laughter.)

1 DR. KEARNEY: It goes on, the whole publication
2 is devoted to brinksmanship in the contract, consultant
3 situation in the Government. And it gives a very, very
4 good exposition of how this works.

5 DR. MOSES: In view of Dr. Brick's remarks,
6 I would recommend that the human health aspects be done
7 first, please.

8 DR. BRICK: Dr. Shepard, did you read that issue?

9 DR. SHEPARD: No, sir, I haven't. I have some
10 homework to do, I see.

11 DR. BRICK: Charlie Peters is the editor of the
12 Washington Monthly, look it up in the phone book and call
13 Charlie up and he'd be glad to give you a complimentary
14 issue of that particular issue. It's a very delightful
15 issue.

16 DR. SHEPARD: Fine, thank you.

17 Yes, sir.

18 DR. SUSKIND: I'm going to be the devil's
19 advocate here for a moment. This is not to disagree, but
20 only to point out an important principle, and that is: if
21 we limit our studies in the field of toxicology to humans,
22 we would know very much less than we do now. That is
23 all I am going to say.

24 DR. SHEPARD: I think we have to look at it
25 from a broad brush perspective.

1 DR. MOSES: yes, absolutely. But I still would
2 like to reinforce the fact that the questions the people
3 really want answered are effects on human health, and any
4 way that you could try to stay in focus. It gets very
5 difficult to stay in focus because most of the data is
6 toxicological data on animals. It is there; it is much
7 easier to control, and it is much clearer. And I hope
8 -- you are aware of that, I'm sure

9 DR. SHEPARD: Well, one of the things that I've
10 asked Jim to look at is the body of data that addresses
11 the industrial exposures, because I think that needs to
12 be brought together, at least in my early perception of
13 the problem. I think that we have a lot of data in various
14 places and one of the reasons that we are so happy to have
15 Dr. Reggiani and Col. Lathrop here today^{is} to perhaps
16 fill in some of those gaps, but I think we really need to
17 take a look at that part of the^(exposure problem) -- this is the human
18 laboratory to a large extent. So, I think that information
19 really needs to be pulled together.

20 I don't know how much of it can be pulled together
21 in this relatively short time-frame, but at least we need
22 to perhaps document what we know and then point to data
23 that still exists or is in the process -- in the pipeline,
24 so to speak, that we can hopefully focus.

25 I think it is also safe to say that this kind of

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1 thing, as Jim has said, is a never-ending evolution.
2 That it will never be complete by the nature of the fact,
3 and so that is why I have also indicated that we need to
4 build into this project a mechanism for tracking on-going
5 information.

6 MR. DeYOUNG: Something that is becoming
7 important, as I think about it, is the question that we've
8 all been kicking over in the past of what weight to
9 give the animal data. How tightly to apply it to humans
10 and I would appreciate it very much, and I'm sure the
11 veterans would appreciate it very much, if this report would
12 help clarify that rather than further muddying that
13 question, which is where it now stands.

14 There is an enormous reticence that we are feel-
15 ing in the VA to use the animal data as basis for disability
16 compensation or for something legalistic, and we need that
17 clarified as much as possible. This critical evaluation
18 can include the weighting to give animal data. That would
19 help tremendously.

20 DR. SHEPARD: Okay. Thank you very much, Jim,
21 it has been a very good discussion, I think, and we will
22 all be following your project with great interest, I am
23 sure.

24 Thank you for sharing it with us.

25 DR. STRIEGEL: Thank you.

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1 DR. SHEPARD: I would now like to move on.

2 I am happy to note that we are well on track.

3 I'd like to call on Col. George Lathrop of the U.S.

4 Air Force.

5 Let's see, George, you need some viewgraphing.

6 COL. LATHROP: Yes, sir, we're going to have
7 to ask you to move.

8 DR. SHEPARD: Okay.

9 Let's just take a moment and stretch...

10 (Brief pause in the meeting.)

11 PRESENTATIONS AND DISCUSSION

12 STATUS OF RANCH HAND STUDY

13 DR. SHEPARD: I would like to introduce Col.
14 George Lathrop, who has been working long and hard on the
15 Ranch Hand Study, an effort that all of us are looking to
16 with a great deal of anticipation and we're indeed very
17 happy that George could take time to be with us and give
18 us an update on the status of the Ranch Hand Study.

19 COL. LATHROP: Thank you very much, Dr. Shepard.

20 I wish to thank the Veterans Administration for
21 the privilege of presenting a study design synopsis of the
22 Air Force Ranch Hand Study, as well as a capsule of its
23 current status.

24 At the outset, I'd wish to underscore the deep
25 and long-standing commitment of the Air Force to conduct

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this study.

The Surgeon General of the Air Force, General Paul Myers, has made numerous trips and personal appearances to reinforce that commitment and to insure that proper and adequate resources are assigned to this project.

Moreover, the Air Force has insisted that this study be conducted with utmost scientific care consistent with the inherent constraint of a sub-optimal population size.

Accordingly, we have subjected/this design to an unprecedented four-stage independent peer review process as well as an assessment by the Interagency Work Group, the latter of which led to the White House direction to proceed with the study.

I'd now like to turn to some basic aspects of the overall epidemiologic study design. The Air Force study goal is straightforward: assess health effects, identify individuals with adverse health effects, both physical and psychological, if such exist.

As a corollary to our primary goal, I think it is clear that any valid medical information arising from this effort will be placed into a mosaic context with other studies to provide a scientific underpinning of the compensation decision.

The purpose of the study is simply to determine

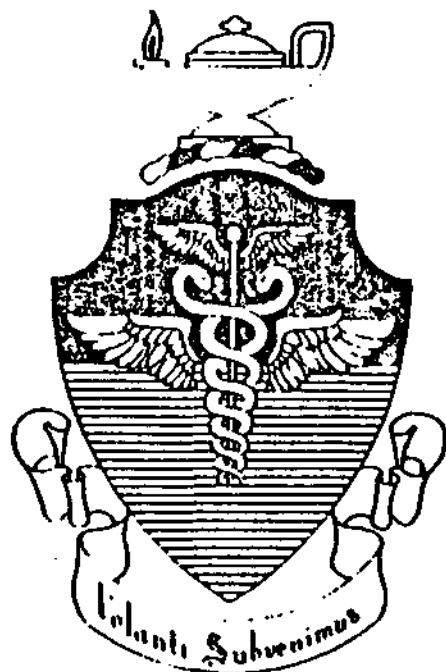
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RANCH HAND II



VIEWGRAPHS ACCOMPANYING
COLONEL LATHROP'S PRESENTATION

USAF SCHOOL OF AEROSPACE MEDICINE
BROOKS AIR FORCE BASE TEXAS

AIR FORCE RANCH HAND STUDY

STUDY GOAL

- **ASSESS HEALTH EFFECTS**
 - **IDENTIFY INDIVIDUALS WITH ADVERSE HEALTH EFFECTS (PHYSICAL AND PSYCHOLOGICAL)**
 - **IDENTIFY OTHERS AT INCREASED RISK**

SPINOFFS: STUDY WILL

- **PROVIDE MEDICAL DATA THAT WILL HELP CLARIFY THE COMPENSATION ISSUE**

PROJECT RANCH HAND II

**PURPOSE OF THE STUDY: TO DETERMINE WHETHER
LONG TERM HEALTH EFFECTS EXIST AND CAN BE
ATTRIBUTED TO OCCUPATIONAL EXPOSURE TO HERBICIDE
ORANGE**

EPIDEMIOLOGIC STUDY DESIGN

COMPONENTS OF THE PROBLEM

HAVE THERE BEEN, ARE THERE CURRENTLY, OR WILL THERE BE IN THE REASONABLY FORESEEABLE FUTURE , ANY ADVERSE HEALTH EFFECTS AMONG FORMER RANCH HAND PERSONNEL CAUSED BY REPEATED OCCUPATIONAL EXPOSURE TO 2,4,5-T HERBICIDE AND ITS CONTAMINANT, TCDD (DIOXIN) ?

AIR FORCE PROJECT RANCH HAND

EPIDEMIOLOGIC APPROACH

48.

STUDY PHASE

METHODS

● **MORTALITY STUDY**

PERSON TRACKING, RECORD REVIEWS

● **MORBIDITY STUDIES**

BASELINE QUESTIONNAIRE, PHYSICAL EXAM

● **RETROSPECTIVE**

● **CROSS-SECTIONAL**

● **FOLLOW-UP STUDY**

ADAPTIVE QUESTIONNAIRES, PHYSICAL EXAMS

THREE PHASE APPROACH REQUESTED

RANCH HAND PERSONNEL

POTENTIAL FOR EXPOSURE

PILOTS, CO-PILOTS, NAVIGATORS

LOW

CREW CHIEFS, MAINTENANCE PERSONNEL

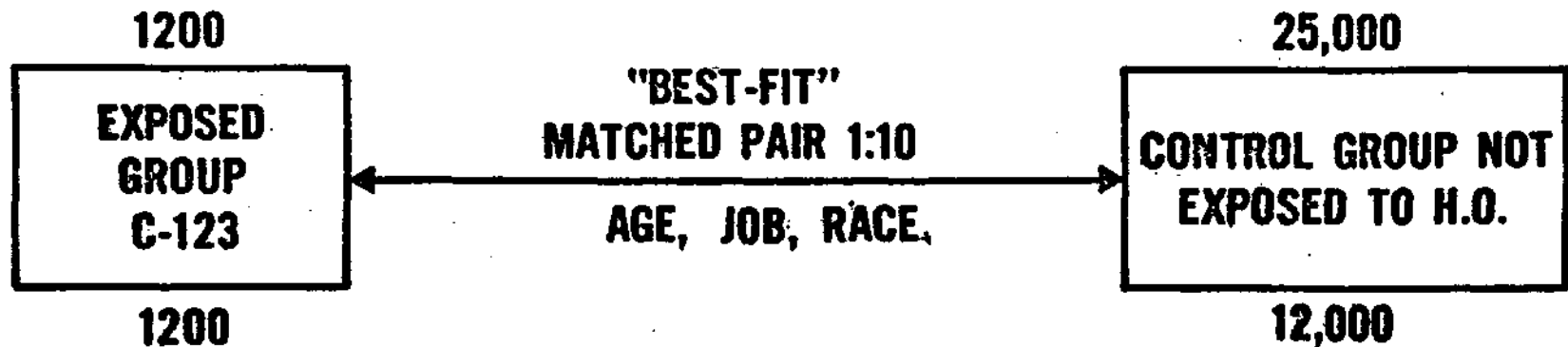
MODERATE

CONSOLE OPERATORS

HIGH

50.

RANCH HAND II
EPIDEMIOLOGIC STUDY DESIGN
RATIONALE FOR MATCHING PROCEDURE



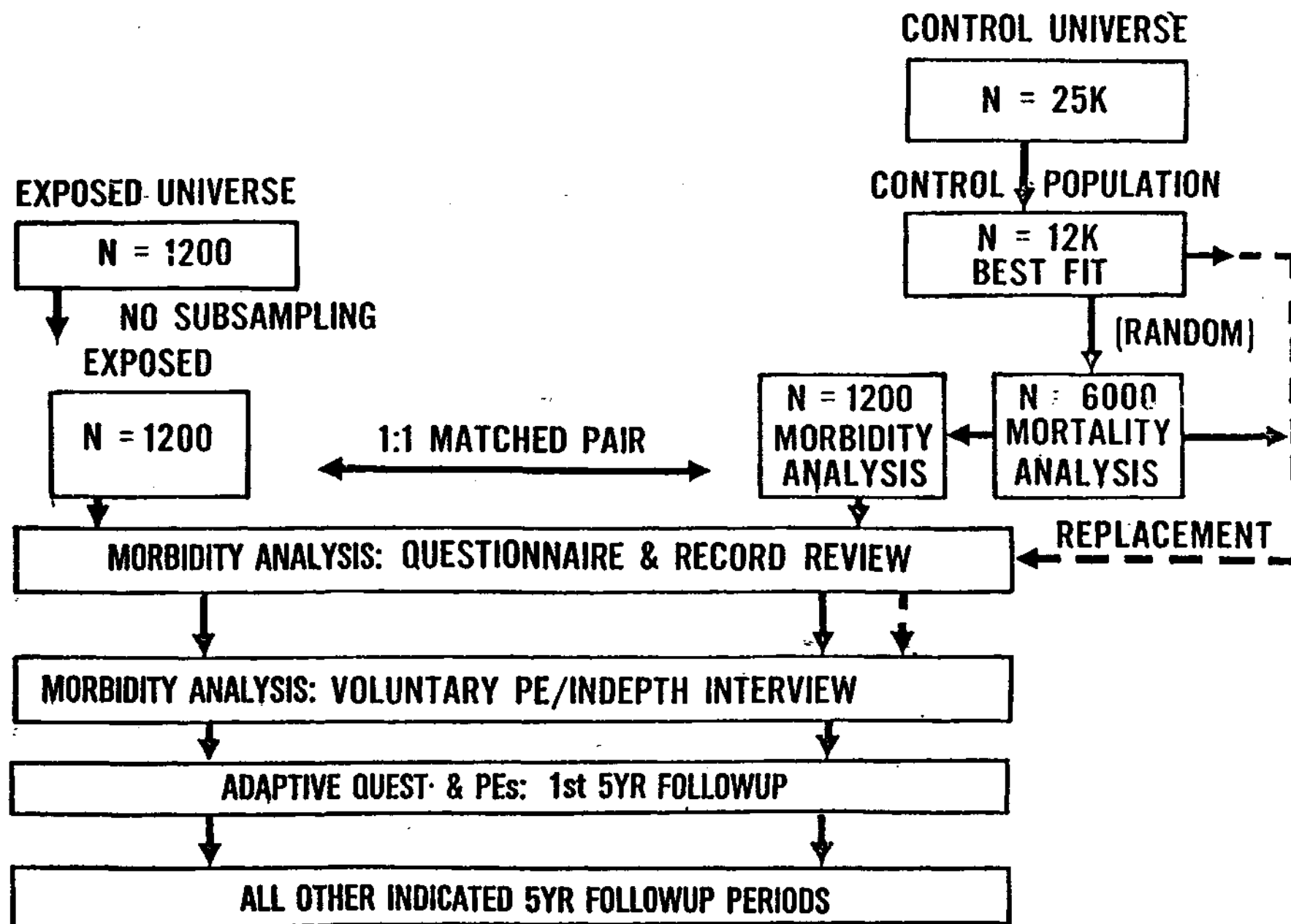
MATCHING PROCEDURE RATIONALE:

- **MAXIMIZES STUDY POWER**

COMPUTER MATCHING
RANCH HAND TO CONTROL, 1:10

- 74.6% EXACT MATCH, BIRTH MONTH, JOB(S), RACE, SEX
- 95.2% \pm 5 MONTHS OF BIRTH, ALL OTHER VARIABLES EXACT
- TIME SPENT IN RVN CONTROLLED BY STRATIFICATION

STUDY DESIGN SCHEMATIC



CURRENT STATUS

- **POPULATION ASCERTAINMENT AND MATCHING ARE COMPLETE**
- **MORTALITY STUDY WELL UNDER WAY**
- **QUESTIONNAIRE DEVELOPED BY NORC AND AWAITING OMB CLEARANCE**
- **PRETEST POPULATION IDENTIFIED**
- **STUDY SCHEDULE DEPENDENT UPON OMB AND D&F PROCESS**

RANCH HAND II FLYING PROFILE

● MILITARY

• ACTIVE DUTY	63
• RESERVE/AIR NATIONAL GUARD	39
TOTAL	102 *

● CIVILIAN

- FEDERAL AVIATION AUTHORITY (FAA)
MEDICAL CERTIFICATES FOR FLYING 88 *

*** FIGURES NOT ADDITIVE**

RANCH HAND II

POPULATION STATUS AS OF 1 DEC 80

● **STATUS OF TOTAL RANCH HAND POPULATION - 1186**

	OFFICER	ENLISTED	TOTAL
* ACTIVE DUTY	128	111	240
RESERVE/AIR NATIONAL GUARD	47	19	66
RETIRED	208	283	491
SEPARATED	50	299	349
DECEASED	24	26	50
TOTAL	458	738	1186

* AVERAGE OF THREE INDIVIDUALS RETIRING MONTHLY

RANCH HAND II MORTALITY STUDY

KNOWN CAUSES OF DEATH AS OF 1 DEC 80

● ACCIDENTAL DEATHS

- KILLED IN ACTION (VIETNAM) 18**
- AIRCRAFT (NONBATTLE CASUALTY) 9**
- OTHER (MOTORCYCLE, AUTO) 2**

● UNKNOWN CAUSE 7

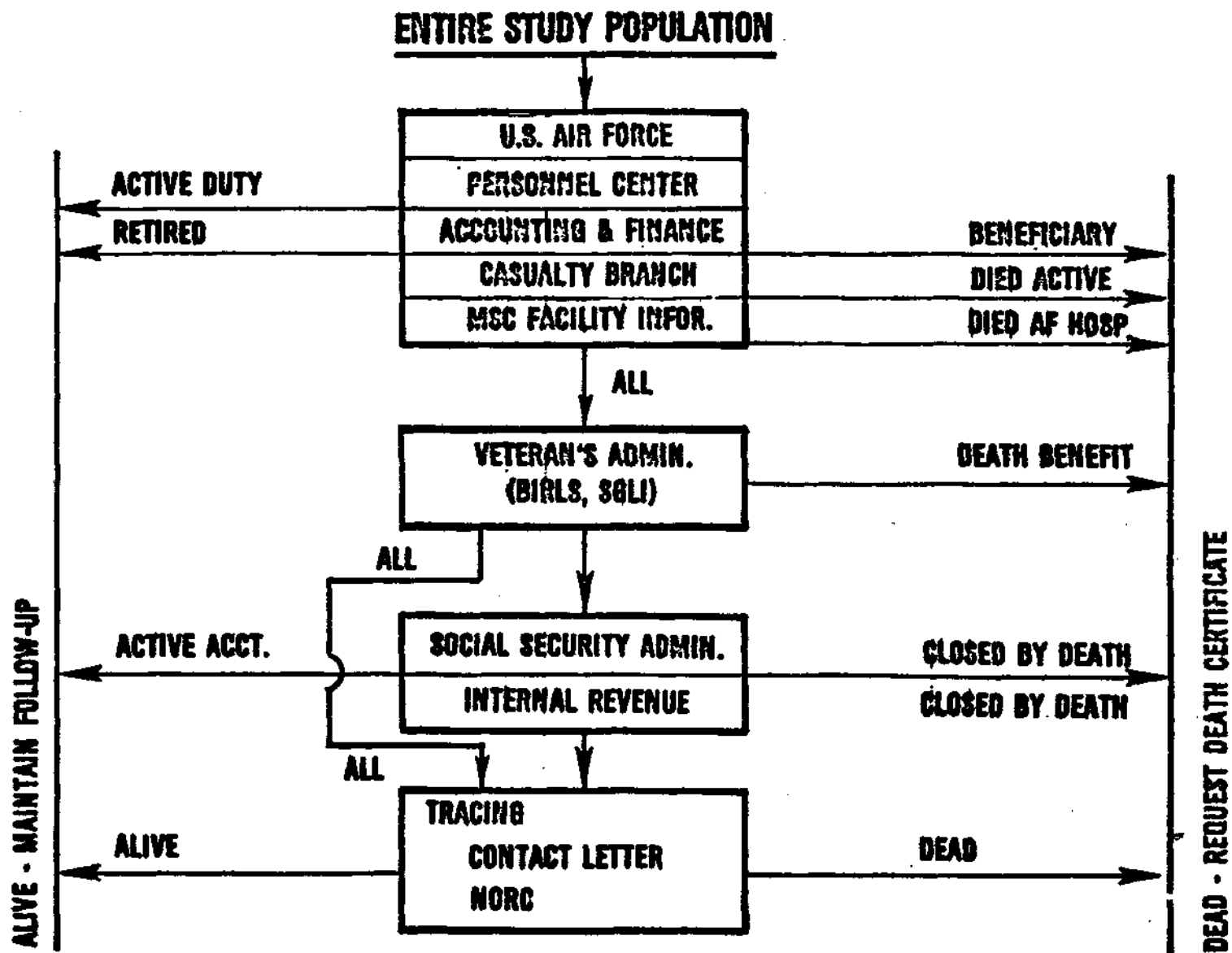
● DISEASE STATES

- HEART 5**
- CANCER (LUNG, RENAL) 3**
- LIVER (CIRRHOSIS) 4**

● SUICIDE 1

TOTAL KNOWN DEAD 50

RANCH HAND II MORTALITY STUDY



1 whether long-term health effects exist, and whether in a
2 cause and effect fashion, we can relate them to exposure
3 to Herbicide Orange.

4 Because of the circumstances of exposure of our
5 population, it is proper to view the issue in terms of
6 time and ask the following question: have there been, as
7 determined by retrospective techniques, or are there
8 currently, as possibly measured by physical examination
9 techniques, or will there be in the reasonably foreseeable
10 future, as measured by comprehensive follow-up studies,
11 any adverse health effects resulting from exposure to the
12 dioxin?

13 To answer the question in terms of time, a three-
14 phased epidemiologic approach is necessary. An overall
15 label for this kind of a study in a nonconcurrent pro-
16 spective study and incorporates a mortality effort, morbid-
17 ity studies and a long-term follow-up study by the
18 techniques and methods that you see outlined here.

19 I would point out that the mortality study will
20 be conducted in-house by Air Force personnel. The morbid-
21 ity studies or physical examinations will be handled by
22 contract to the Air Force. Questionnaire techniques will
23 also be handled by civilian organizations under contract
24 to the Air Force.

25 In terms of exposure to Herbicide Orange, our

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1 study subjects fall into three broad categories, as you
2 see depicted here. The folks who sat up front in the
3 aircraft, in our judgment, received reasonably low exposure
4 to the herbicide;

5 the crew chiefs and folks who took care of the
6 aircraft, a moderate exposure. The people who received
7 tremendous doses of the herbicide were the enlisted
8 personnel located in the rear of the aircraft who operated
9 the console tank containing the herbicide.

10 We have capitalized on these qualitative differ-
11 ences and have recently conducted some operational herbi-
12 cide simulation studies in aircraft to quantify these
13 differences in exposure.

14 And exposure index will be calculated and will
15 be used in a regression or covariant sense to any detected
16 clinical end point in the study.

17 In addition, I would point out that even under
18 conservative biomathematical models, the ranch handlers
19 received approximately 1,000 times^a higher dose than the
20 average dose of an average ground troop.

21 We have chosen a tightly matched pair design to
22 provide maximum statistical power, vis-a-vis primary
23 stratification techniques. Our population size is
24 roughly 1,200. Our control universe is roughly 25,000.
25 We will make a 1 to 10 best fit match to give us a

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1 control population of approximately 12,000.

2 While we cite here that we're actually measuring
3 or controlling for three variables, we are actually
4 controlling for four since all members of both the ranch
5 hand and control population are male.

6 I think these statistics verify the high degree
7 of matching precision that we are able to achieve. 75 per-
8 cent of our controls matched exactly down to the month
9 of birth with all other variables matched exactly to each
10 ranch hander. Moreover, 95 percent can be matched plus
11 or minus five months of birth.

12 Initially we felt that we would like to match
13 for the time spent in Vietnam, but computer records were
14 inadequate to make this as a proper match variable and,
15 therefore, our plans at this time include stratification
16 at analysis to take this into account.

17 As important as the degree of match, I would
18 point out that our control group is essentially pure and
19 was definitely not exposed to herbicides to a significant
20 degree. Other contemplated studies of military population,
21 which lack this feature, clear cut exposure/nonexposure,
22 will ultimately be subjected to a substantial dilutional
23 bias in our judgment.

24 This is a complex slide that gives you the overall
25 picture of the epidemiologic study design. As you can see

1 on the left, our universe is roughly 1,200 for the ranch
2 handers. We plan absolutely no sub-sampling within
3 that group. Our control universe starts at about 25,000.
4 With a 1 to 10 match, we then fall to 12,000. We'll take
5 a 50 percent random sample of that group, clearly matched
6 to the ranch handers to designate a mortality study of a
7 1 to 5 design.

8 As you can see from that point, members are
9 selected from the mortality cohorts in a pair design,
10 giving us a 1 to 1 pair design for both the questionnaire
11 and physical examination aspects.

12 Yes?

13 DR. GROSS: Col. Lathrop, what is the
14 distribution of those 1,200 exposed, that you call, ranch
15 handers in terms of this low, middle and high exposure
16 to pilots, to console operators?

17 COL. LATHROP: I have a graph later on that
18 basically gives those in sequence.

19 DR. GROSS: When you say "ranch handers,"
20 that includes all of them?

21 COL. LATHROP: That includes everybody.

22 DR. GROSS: I see.

23 COL. LATHROP: And I am not sure it has always
24 been clear, but there are probably members within the
25 ranch hand group that received zero exposure.

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1 DR. MOSES: How would that happen?

2 COL. LATHROP: Administrative officers who never
3 got into the aircraft.

4 Nevertheless, the only mechanism we have to
5 identify the ranch handlers is exhaustive searches through
6 our computer records and archives to come up with a very
7 discrete population designated as our study population.

8 Because there will be a graded difference of
9 exposure between / enlisted and officers, again, using the
10 mathematical models that we have developed, we can then
11 estimate an exposure dose for each individual. That is
12 one of the key strengths of the ranch hand study, the fact
13 that we will be able to use that exposure concept as we
14 see clinical endpoints emerge within the study.

15 I would point out that our follow-ups are set
16 for a minimum of 20 years and are designated specifically
17 for years 3, 5, 10, 15 and 20.

18 As to current status, matching is totally com-
19 plete. The mortality study is well underway at this time
20 and I will show you figures on that in just a moment.

21 A questionnaire to be administered to both study
22 and control members has been developed by the National
23 Opinion Research Center and we are currently awaiting OMB
24 clearance before administering that. We have a pre-test
25 population identified. We are set to go. Our entire

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1 schedule is now set to the OMB clearance.

2 I've mentioned the D&F process, determination
3 and finding process. I am informed by Major Brown of the
4 Surgeon General's Office that that possible delay no
5 longer applies and so we are now dealing apparently
6 strictly with an OMB clearance problem.

7 To give you an idea of some of the features of
8 our flying population, many of them are still actively
9 flying, both military and civilian. This can conceivably
10 present some problems in terms of physical examinations
11 within the study itself.

12 As pointed out here in the slide, these figures
13 are not particularly additive at this point. We have
14 requested the FAA to clarify those on flying status by
15 tracking them out as to exact flying category.

16 Exact population size is 1,196, broken down into
17 the following distribution, Dr. Gross, this roughly
18 answers your question. About 20 percent of our people
19 are still in active duty; 5 percent reserve or National
20 Guard; 40 percent retired; 30 percent separated; roughly
21 5 percent deceased at this time.

22 In terms of accrued exposure categories, Dr.
23 Gross, they would fall in the officer and enlisted
24 category for the moment, but actually we've split down
25 specific jobs in terms of a matching variable into five

1 separate categories.

2 As of this time, we have 50 recorded deaths with-
3 in the ranch hand population, distributed as you see here.
4 It is apparent that most are involved in aircraft accidents
5 automobile accidents, and so forth. We are actively
6 pursuing the seven of unknown cause at this time.

7 This is a schematic to show you the various steps
8 to properly conduct a mortality study within our current
9 administrative set-up. As you can see, the top block
10 represents going through the Air Force personnel^{and} financial
11 systems; both the ranch hand and control population have
12 passed this point. We have now entered both computer tapes
13 into the VA system and we are somewhat anxious to get the
14 results back. We are promised preliminary results some-
15 where on the order of three weeks from now.

16 Following that point, we will enter the Social
17 Security and IRS system to make further determinations as
18 to alive/dead status. Our primary difficulty at that point,
19 once we gather all deaths from both the study and the
20 control group, will be to pursue death certificates, and,
21 more importantly, to take those death certificates and
22 specifically correlate them to all known medical records
23 on each individual within the study.

24 In summary, the Air Force is well down the road
25 in conducting a detailed and comprehensive epidemiologic

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1 study, one that we believe is worthy of the issue itself.

2 Mr. Chairman, I thank you for the kind invitation
3 to speak to your group today.

4 DR. SHEPARD: Thank you very much, Col. Lathrop,
5 it was very enlightening. We, as I say, endorse your
6 and efforts/are following your pursuits with great interest.

7 Yes?

8 DR. MOSES: Maybe I missed it, but I didn't
9 realize the numbers for the low, moderate and high exposure
10 groups, the numbers of people that will be in the study
11 that are in those groups? Do you roughly know what that
12 is?

13 COL. LATHROP: Yes, we know. We just didn't
14 have the appropriate slide and I would hope to answer Dr.
15 Gross' question by a crude breakout of those still on
16 active duty, officer and enlisted.

17 I would also point out, as we've had the pleasure
18 of going through four peer reviews on this, the normal
19 review time for this particular protocol is eight hours
20 and we've seen it extended to 16 hours. So, I will apologize
21 if I've omitted details with you today.

22 DR. SHEPARD: Dr. Kolbye?

23 DR. KOLBYE: First a request. I would appreciate
24 if it is possible to include the slides in the transcript
25 so that when we are reading the transcript of the proceed-

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1 ings here, we see the slides, if that's possible. Just
2 submit some Xeroxes.

3 Secondly, in terms of prospectively tracking the
4 mortality of these populations, are you matching for other
5 characteristics so that you are hopefully able to sort
6 out some of the risk factors like smoking and diet, which
7 can markedly influence the incidence of cancer -- and
8 alcohol intake?

9 COL. LATHROP: The match would perhaps be an
10 incorrect terminology.

11 DR. KOLBYE: Okay.

12 COL. LATHROP: We will clearly stratify for those
13 variables to be sure.

14 DR. KOLBYE: Fine, thank you.

15 DR. SHEPARD: Yes, David?

16 DR. ERICKSON: Colonel, at one point in time
17 I believe you were concerned that a number of officers
18 would be commercial pilots at this time. Do you
19 have any further information on it?

20 COL. LATHROP: We have not been able to clarify
21 the FAA figures further than what I have shown today.
22 We will simply have to see the various categories of the
23 flying certificates that FAA has given out. Many of the
24 folks that are separated or retired fly as a hobby and not
25 necessarily in the 747 above you right now. But we need

1 to know the exact figure to be sure, and we will do so.

2 MR. DeYOUNG: Possibly I missed it earlier,
3 where is that 25,000 control universe drawn from? Those
4 are Airmen of one sort or another?

5 COL. LATHROP: These are Airmen, both officers
6 and enlisted specifically flying cargo aircraft in the
7 Vietnam environment. We felt it very, very important to
8 select a control population that was exposed
9 to the same environmental circumstances as our study
10 population.

11 MR. DeYOUNG: But they are people with Vietnam
12 service?

13 COL. LATHROP: Oh, yes, to be sure.

14 MR. DeYOUNG: Okay.

15 COL. LATHROP: Well, let me categorize that.
16 They spent a great deal of time in Vietnam. They may
17 not specifically have been assigned to Vietnam.

18 MR. DeYOUNG: Meaning they might have flown in
19 and out?

20 COL. LATHROP: Surely.

21 MR. DeYOUNG: Oh, I see.

22 Also, in conversation with some Army types and
23 Air Force, I can't be real certain at this moment, whether
24 the man was an Army flyer or an Air Force flyer who I
25 talked to, but I recall him telling me a story of the

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1 time the fill nozzle stuck open on one of the tanks and
2 the Herbicide Orange spouted up and out of the tank and
3 showered the crew. Will this kind of unusual, but high
4 significant exposure be dealt with in the questionnaires
5 that lead up to this?

6 COL. LATHROP: Yes.

7 MR. DeYOUNG: That will be taken into account?

8 COL. LATHROP: We think that is very important,
9 Mr. DeYoung. We grant that that is obviously a subjective
10 means of looking at the exposure, but we are obliged to
11 do so. The anecdotal stories of many of these flyers are
12 genuinely terrifying. One would not expect a pilot and
13 navigator sitting up front in the aircraft to get outside
14 the aircraft literally with their flight suits dripping
15 with the herbicide, but that, in fact, was the case in
16 many circumstances.

17 Again, we've done the simulation studies to look
18 at the vapor trails within those aircraft in various
19 operational configurations, i.e., flying 150 knots indica-
20 ted air speed, 150 feet off the deck with the rear cargo
21 door open. All pilots and navigators flew with the cock-
22 pit windows open because of the intense ground fire. And
23 what happened when one of those pipes burst, that you are
24 talking about, or that main tank took a hit, that vapor
25 was literally pulled forward into the aircraft and out

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1 the cockpit windows. So, the folks up front, indeed,
2 received very substantial exposure, but, again, in relative
3 terms nothing like the poor fellow in the back. He was
4 doused repeatedly.

5 MR. DeYOUNG: All right. What I am asking, I
6 think, in generic form is you are not going to be married
7 to that mathematical model --

8 COL. LATHROP: Oh, no.

9 MR. DeYOUNG: -- when the anecdotal information
10 shows up?

11 COL. LATHROP: No. As a matter of fact, when
12 you do mathematical models, you can easily put in subjec-
13 tive data into those and caveat it in a variety of circum-
14 stances.

15 DR. SHEPARD: Dr. Suskind?

16 DR. SUSKIND: I am going to ask some questions
17 about the protocol and the implementation for the morbidity
18 study. I gather it is going to have several parts?

19 COL. LATHROP: Yes.

20 DR. SUSKIND: One will be a questionnaire --

21 COL. LATHROP: Yes.

22 DR. SUSKIND: -- and then a hands-on examination
23 with everything that that entails. Can you tell us a
24 little bit about the nature of the questionnaire with
25 respect to your own requirements, as well as what the

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1 contractor may have as a point of view about getting
2 information to the participation of the examining physician
3 -- the participation of the examining physician in
4 eliciting critical historic information which has to
5 relate to past morbidity, as well as current health effects?
6 Here it is, 15 years away from exposure, people may have
7 had--hypothetically--have had chloracne for two or three
8 years and then it disappeared, but that is an important
9 historic piece of information with respect to morbidity.

10 COL. LATHROP: That is a giant question, Dr.
11 Suskind, and I am not sure I can adequately answer it,
12 except to say that we have taken extreme care to assure
13 that the various study phases are done, in essence, by
14 blind protocol assessment. That is, the results of that
15 questionnaire will not be revealed to the examining
16 physician. The review^{of} systems to be conducted for the
17 physical examination will not be revealed to the primary
18 examining physicians.

19
20 There will be an examination collator, if you
21 will, a master internist who will take all laboratory
22 data, historical data, physical examination data and
23 attempt to put them into context for a diagnosis. We
24 grant that this is a very unusual way of conducting a
25 physical examination, but we feel that because of the

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1 controversy with regard to many of the clinical end points,
2 one is obliged to do this on a blind basis.

3 To specifically get into the questionnaire, we
4 have attempted to mirror the thrust of the physical
5 examination to the questionnaire. Our primary purpose
6 of using questionnaire techniques is to capture data that
7 would ordinarily be lost under low compliance rates.

8 So, we are attempting to gather by questionnaire
9 some aspect of what we are also going to be detecting,
10 hopefully, at physical examination.

11 DR. SUSKIND: May I just ask one other question?

12 Then the examining physician is largely going
13 to be examining without questioning?

14 COL. LATHROP: That is correct.

15 DR. SUSKIND: That has its problems.

16 COL. LATHROP: Yes, but certainly within his
17 sphere of diagnostic capability, he will obviously be
18 free to ask any questions related to his particular area
19 of expertise, including past review of systems.

20 DR. SUSKIND: Okay.

21 DR. KEARNEY: Col. Lathrop, you spent consider-
22 able time with your people at the White House meeting
23 overgoing your study. I think you spent six hours with
24 us, and one of the issues that came up there, and I think
25 it is critical to your evaluation, is the degree at which

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1 you can get commercial pilots, who are now commercial
2 pilots, to participate in your study.

3 You remember that commercial pilots are extremely
4 reluctant to undergo physicals other than what he needs
5 to get his license.

6 COL. LATHROP: Any pilot.

7 DR. KEARNEY: Any pilot. And it seems to me
8 that this is a critical population because we have here
9 an able-bodied population and if these are not included in
10 the study, it may skew it to the left or right. Have you
11 resolved the issue of participation of commercial pilots
12 in this study?

13 COL. LATHROP No. Again, we well recognize
14 the potential for that problem to exist, we would hope
15 that in our one on one interaction with these
16 individuals that we would be able to persuade them to
17 volunteer for one more herbicide mission, if you will,
18 and participate in the study. It is a totally voluntary
19 study, absolutely no coercion will be used to gain entry
20 to the study. We are still exploring a variety of
21 mechanisms to induce participation of all study members,
22 and that includes pilots as well.

23 MR. DeYOUNG: I would like to echo Dr. Kearney's
24 concerns on this issue. I had a very long conversation
25 a year or so ago with a man who was at that time flying

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1 helicopters, commercial for an off-shore oil company.
2 He took himself off flight status, for which I have an
3 enormous respect for the man, because he said his temper
4 and personality was to the point where he did not trust
5 his own judgment in the aircraft any longer. And I
6 think you are going to have the devil's own time trying
7 to get this kind of information from these particular
8 people. I think we are going to have a bad enough time
9 with the physiological problems, but if you start looking
10 into the realm of personality changes and psychology, I
11 think it is going to become even more evasive.

12 I have some serious reservations about the re-
13 sults specifically in that area.

14 COL. LATHROP: Well, I believe overall that that
15 issue will be balanced because the problem will equally
16 exist with members of the control group.

17 DR. SHEPARD: Thank you very much, Col. Lathrop.
18 I really appreciate your remarks.

19 I think I am going to deviate from the agenda
20 a little bit. Since we are talking about people flying
21 missions, using defoliants, I think we will now here from
22 our friends from the civilian sector, Mr. Harold Collins
23 and Dr. Clifford Roan.

24 Mr. Collins, would you like to come up and
25 introduce yourself.

CROP DUSTER STUDY (REPRODUCTIVE MORTALITY
AND MORBIDITY - PESTICIDE EXPOSURE)

DR. SHEPARD: We are very fortunate to have these gentlemen with us this morning because they represent the, should I say, a similar group of individuals who have been involved in the agricultural and forestry use of herbicides.

Mr. Collins?

MR. COLLINS: Dr. Shepard, good morning; ladies and gentlemen.

We have brought with us this morning copies of the original NAAA / Health Survey delivered to my association by Dr. Roan of Hopes consulting, Inc. These documents / are for distribution now to any of you who would like them.

My name is Harold Collins and I am employed by the National Agricultural Aviation Association as their Assistant Executive Director and Director of Government Affairs. We are headquartered in Washington, D.C. national The / association is a federation of state associations throughout the United States.

Our membership includes agricultural aviation businesses, which we refer to as ag operators; it includes agricultural pilots, allied industry representatives from those entities which supply either product or services to our ag operators, and international individuals or companies who have a common interest in agricultural aviation.

1 Now, the reason for NAAA's participation in
2 this meeting today is to provide this advisory committee
3 with the reasons for and the results of an association
4 sponsored epidemiological study of ag pilots and their
5 families. The title of this study is: "An Investigation
6 of the Possible Effects of Pesticide Exposures on
7 Reproductive Mortality and Morbidity."

8 With me today is Dr. Clifford C. Roan, senior
9 consultant for Hopes Consulting, Inc. HCI
10 conducted this study for NAAA. Following my descrip-
11 tion of the beginnings and purposes of this study, Dr.
12 Roan will summarize the results, following which we will
13 try to answers any questions which you may have.

14 Initiation of the NAAA study was formally
15 accomplished in 1978. At that time, the controversy be-
16 tween those for and those against pesticide use had been
17 underway since the 1950s. Notwithstanding more than two
18 decades of study, the public was still denied a resolution
19 to the dispute.

20 There seemed to be no acceptable way to equate
21 pesticide exposure in controlled laboratory studies on
22 animals with the real world exposure among humans.
23 That assumption led / the association some interesting conclusions.

24 Ag pilots in this country are voluntarily and
25 repetitively exposed to pesticides at levels greater than

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1 the general public. Since most agricultural aviation
2 operations are small businesses, it happens that spouses
3 of ag pilots often serve as mixers, loaders, and flaggers
4 for pesticide operations during the early years of the
5 business. This exposure happens to coincide very often
6 with the primary child-bearing years of that spouse.

7 It seemed logical, therefore, to us that a
8 health study of ag pilots and their families would provide
9 an excellent source of information to help determine the
10 impact of pesticides on human health.

11 In that regard, NAAA sent letters to the United
12 States Environmental Protection Agency, the United States
13 Department of Agriculture and the Federal Aviation Adminis-
14 tration requesting their financial assistance to conduct
15 this project.

16 Following receipt of negative responses to all
17 of these requests, the Associations' Board of Directors
18 approved funding of the project as long as that study
19 would be scientifically adequate considering our limited
20 resources.

21 Hopes Consulting Incorporated designed that
22 study, which met the Board's standards. The study was
23 implemented under the following conditions: One, a review
24 of the proposed study by qualified scientists prior to
25 its initiation.

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1 Two, confidentiality of the information for
2 individual study participants.

3 Three, ^{full} payment of the HCI fee for conducting the
4 study in full prior to the beginning of the analysis of
5 the data.

6 Four, approval for HCI scientists to publish
7 independent reports on the data without any future NAAA
8 approval, and, finally, five, provide NAAA with peer review
9 of all subsequent published reports.

10 To date, all of these conditions have been met
11 The first public report on this study was presented on
12 December 3, 1980 during NAAA's annual convention in Las
13 Vegas, Nevada.

14 That report has been made available to you here
15 today. It demonstrates that ag pilots and their families
16 do not experience reproductive mortalities and morbidities
17 different from the siblings of ^{ag pilots} / in spite of their higher
18 and repetitive exposure to pesticides.

19 Association members believe that this study
20 is a unique and substantial health documentation which
21 must be considered when evaluating the effect of pesticides
22 on human health. NAAA further hopes that future reports
23 developed from the data base already on hand will be
24 similarly valuable.

25 This Association has many veterans in its member-

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1 ship. For this reason, we are especially pleased to offer
2 the NAAA ^{report} to the Veterans Administration for review and
3 evaluation. We share the concerns of veterans and others
4 regarding human physical ailments attributed to pesticide
5 exposure.

6 We are equally concerned, however, that the
7 enormous publicity given to pesticides could detract from
8 scientific and medical detection of other potential sources
9 for these human sufferings.

10 NAAA will continue to support and endorse efforts
11 that will further reduce the potential for human exposure
12 to pesticides. We hope that studies of other popula-
13 tions, groups who are exposed to pesticides, ^{also} will be
14 further developed for your consideration.

15 And, now, I ask Dr. Clifford Roan to present
16 the details of the NAAA study.

17 DR. ROAN: I would have to say for those of you-
18 all on the panel who happen to be epidemiologists, you
19 have my sympathy. I regard an epidemiologist as a seriously
20 handicapped scientist .

21 (Laughter.)

22 DR. ROAN: If I were to do this study over, I
23 would probably do it on the basis that alphabet A through
24 L would breed on the last day of odd numbered months and
25 odd numbered years, and N through Z the converse of that,

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1 and I would dictate who bred with who.

2 (Laughter.)

3 DR. ROAN:

4
5
6
7 Our data that you have before you are based on a pilot and
8 his reproductive performance of record versus that of a
9 sibling, and their reproductive performance of record.

10 This gives us about as good a sociological
11 demographic match as you can come up with. I am facetious
12 by nature and I have to observe that epidemiologically a
13 divorce and remarriage is also an abomination. Whose
14 children are we talking about?

15 The data that we have may appear to you as
16 though we were deliberating juggling the population base.
17 We were not. These questionnaires were distributed based
18 on the fact that it was his money, his wife, his children,
19 the Association. We figured that 75 percent of them
20 might respond. So we provided questionnaires in sets, one
21 for the pilot and one for the sibling for 75 percent of
22 their membership of record in their 1979 membership
23 directory. We provided all others that they might ask
24 for if they wanted more.

25 And then we took back what we got. It was truly

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1 voluntary. As they came in, it indicated on the cover
2 sheet that it was a pilot, the pilot's brother, or a pilot's
3 brother-in-law. They had the same serial number basically
4 on the form. We considered that initially we had a
5 matched set.

6 Then we discovered that not all pilots were
7 married and had progeny of record, at least. So, since
8 we were studying reproductive mortality and morbidity that
9 had to drop out. I'm just being honest.

10 (Laughter.)

11 DR. ROAN: Then we went a little further and
12 we found a grave mistake in design of the project, and
13 that is that the male was primarily the exposed person.
14 We have, as Harold said, some wives who have acted in
15 varying capacities, but there was not a very great number
16 of those. So, on reproductive morbidity, birth defects,
17 we requested that information only from the male part of
18 the form.

19 This would seem insignificant if it weren't for
20 the fact that sometimes a
21 sibling, the sister, for instance, would answer the
22 questionnaire completely, her part, the female part. We
23 had no data from the male. We had the same thing occurring
24 in the other half.

25 The brother would answer all the questions and

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1 the sister-in-law would say it is none of your damned
2 business what pregnancies I had prior to marriage, which
3 was one question we asked. And we just didn't get them.

4 So, really, these are -- the data you have are
5 matched the way they came in. We didn't juggle anything.

6 I'll give you the conclusions right now.

7 This is the population, a group of agricultural pilots
8 and their reproductive performance contrasted with siblings
9 and their reproductive performance. You have copies of
10 the questionnaire and the report that you have before you
11 and can see just how we got the information.

12 Now, this distribution of data returns is
13 purely arbitrary. I just drew lines, divided it in four
14 quadrants. I could divide them up any other way you want
15 to. We have them coded by state. We have them coded a
16 number of ways,

17 This is what we got in. We cut them off on the
18 30th of June 1980. That is what we have in our files.
19 Now, they aren't matched obviously all the way along.
20 All we are talking about now, the data you will see, are
21 pilots and matched siblings. Grossly matched. Page one,
22 it's a brother or brother-in-law. And we went on down
23 and we found out we had to throw them out.

24 DR. MOSES: Excuse me.

25 DR. ROAN: Yes.

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1 DR. MOSES: How many did you send out? What
2 does that represent? Is it 20, 30, 50, 100?

3 DR. ROAN: We sent out over 1,200 sets.

4 DR. MOSES: Does that mean 2,400 people then?

5 DR. ROAN: Yes.

6 DR. MOSES: 1,200 sets, 2,400 people?

7 DR. ROAN: A pilot and some siblings. And we
8 got a -- you can add them up there, the total returns we
9 got.

10 DR. MOSES: Yes, I already did.

11 DR. ROAN: Remember, this was voluntary; there
12 was nothing compulsory on these people.

13 We followed up.

14 DR. MOSES: 592 is what I get.

15 DR. ROAN: Yes, that sounds about right. The
16 match -- we'll come down to the matched populations in
17 detail a bit later.

18 DR. MOSES: So about 25 percent then?

19 DR. ROAN: Came back.

20 DR. MOSES: Less than 25 percent?

21 DR. ROAN: Yes. Actually, which isn't too bad
22 on a mail questionnaire, essentially a mail questionnaire
23 that is voluntary, send it in and you look at all the
24 questions we asked. We would have like to have had 350
25 matched sets, but we had to work with what we had. The

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1 population is not all that great, but it is the best there
2 is.

3 All right. Now, you see right away we begin to
4 have differences in match. They don't come out the way
5 they should, but, in general, this is merely to demonstrate
6 with reference to age, weight, height, age, education,
7 these populations were basically similar, which isn't
8 amazing for siblings.

9 Now, their general reproductive performance,
10 these are where we had matched data either from the male
11 or the female. Regionally, they bred about the same in the
12 northwest as they did in the southeast and there is no
13 statistical difference between pilots and siblings in the
14 gross number of pregnancies.

15 All right. The number of pregnancies of
16 pilots wives versus the pilots sisters and the pilots
17 wives where there were sisters-in-law. We subdivided
18 the population, the pilots with sisters and the pilots
19 with brothers. And there are no statistical differences
20 in these matched T-tests, just establishing a little bit
21 more that the population to the extent possible, were
22 comparable.

23 The distribution of pregnancies by age. There
24 is no significant difference in these data as to when the
25 pilot's wives, compared to the pilot's sister. Another

1 population of pilot's wives which differs from the first
2 group because they had only sisters-in-laws that we
3 could compare.

4 So, their breeding age was essentially the same.

5 Now, putting them all together in one lump sum,
6 that is, just combining the other two, the age of the
7 mother when the event occurs of any birth. I'll have to
8 go back and look that one up because that refers just to
9 miscarriages, and I think it probably does.

10 There were no differences.

11 Now, live births, miscarriages and still births,
12 this includes birth defects. This, I would define as
13 reproductive mortality. Here again, regionally, based on
14 these artificial regions, there are no differences.

15 Now, there are two ways of doing this, and not
16 being that much of a statistician, but we did have
17 statistical advice so I did it both ways, the number of
18 incidents per family live births versus miscarriages and
19 still births, I can't explain this; this is the way it
20 came out. The siblings had a higher rate of miscarriages
21 and still births than the ag aviation families. This is
22 the way it came out.

23 When we considered the number of individuals
24 that experienced these, there were no differences.

25 The fact has been explained to me by Dr. Matanoski

1 that the fact that an individual has one or more miscar-
2 riages is more significant for this study than if they had
3 half a dozen. So, we've got it both ways.

4 Now, we've got birth defects. Our big problem
5 was we asked for birth defects only the male part of the
6 form. So, we have a different side of the population,
7 but anyway you slice it, there are no differences in these
8 data as tabulated here.

9 Now, we went to another statistical technique
10 for evaluation, matched from our binomial distribution,
11 we looked rather diligently to detect differences; to see
12 if there were any, and there were none.

13 Now, we took all pilots and brothers-in-law,
14 no difference.

15 I guess that's all of them.

16 Now, some other thing we did, which we haven't
17 got recorded, we had quite a list of birth defects from
18 trivial to those that were regarded as being highly
19 significant. So, we grouped these out to see if one
20 classification of birth defect was masking another. We
21 found no differences there.

22 We started grossly. First of all, we find out
23 whether there were any differences in the population. If
24 there were, then we would work our way down and try to
25 find out why. Now, the data you do have before you, which

1 we haven't analyzed completely yet, we asked these pilots
2 what kind of chemicals they had worked with since they
3 had been in the business by the category of chemicals,
4 insecticides, fungicides, herbicides, et cetera, all the
5 way down, and the years in which they worked with them.

6 Then we asked what crop they had spent their time
7 treating because knowing the crop they were treating; know-
8 ing the decade in which they were doing it, we could pretty
9 well reconstruct what they were exposed to.

10 Right now we have an argument among the team
11 doing this as to how much further we should go in massaging
12 these data to see where the differences fall out.

13 We have another meeting scheduled for the 27th
14 to debate what we should do, or should have done with the
15 data.

16 I would like to acknowledge that what you see
17 before you are my words, mine exclusively. You will also
18 see a listing of the team that worked on that. Dr.

19 Matanoski , an epidemiologist; Dr. Trout, a statistician;
20 Fritzi Pylant a systems analyst; Ken Olds
21 a pesticide chemist; Peggy Wheeler, a public
22 health nurse and Carolyn McIlnay a home econo-
23 mist.

24 These are the people that basically designed the
25 questionnaire and told me what to do. And I have, to the

1 best of my ability followed their advice and instructions.
2 This is a preliminary report. There is a lot more to be
3 done.

4 When you look at the questionnaire, we've got
5 data on cancer. I heard somebody asking earlier about
6 smoking and drinking; we have that on both the male and
7 female. All of these data will ultimately be ferreted
8 out and we will see what we can find out.

9 Now, the next stage -- I don't know which way
10 to go -- we can take this matched population and we can
11 go into everything we've got on them, or we can take the
12 greater population, which is unmatched, and see what those
13 characteristics are as far as initially reproductive
14 mortality and morbidity.

15 We did do one other thing for those who are
16 epidemiologically oriented, Dr. Matanoski, is a female,
17 and I discovered several differences between males and
18 females, more than I knew existed, but in this case it
19 seems that females tend to be more sensitive to significant
20 life events than males. Therefore, the pilot, if he
21 filled out the form, might not remember all the miscarriages
22 his wife or wives had. And this is reasonable.

23 So, we checked the female versus the male and we
24 could find no differences in that reporting. In fact,
25 in most cases where the form is filled out completely, it

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1 was in one set of handwriting. This is not a statistical,
2 scientific verification; this is a sensation from looking
3 at it and it is exactly what I would do, / I get a
4 questionnaire like this, I would ask my wife. And I
5 think this is what happened here in many cases.

6 I couldn't tell you when my father died right
7 now, but my wife could.

8 Now, do you have any questions on what we've
9 done ?

10 Yes, sir.

11 DR. SHEPARD: You may have mentioned it and I
12 may have missed ^{it} /, did you give us the distribution of
13 the kinds of herbicides that were used?

14 DR. ROAN: No, sir.

15 DR. SHEPARD: Okay. Is there any assessment
16 of that -- of the data?

17 DR. ROAN: I have it. I have that available.

18 DR. SHEPARD: Okay,

19 DR. ROAN: We just haven't ferreted that out yet
20 because we had no differences.

21 DR. SHEPARD: Okay, fine. I just wondered
22 -- just in a broad brush sense, was 2,4,5-T heavily
23 represented in the herbicides you used?

24 DR. ROAN: In certain areas, yes. That on people
25 who had been working in the Great Plains area on wheat,

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1 that is what they put the most of on.

2 MR. COLLINS: In the questionnaire, Dr. Shepard,
3 the question is: do you work with phenoxy-type herbicides
4 or have you, and within which time frame?

5 We would be able to detect then by area of
6 country and go back and verify those who worked on range
7 land, rights-of-way where you might expect products like
8 2,4,5-T and 2,4-D to have been used.

9 DR. HODDER: When you say the sibs of pilots
10 I got the impression you sent one questionnaire --

11 DR. ROAN: A set. 2 questionnaires bearing
12 identical serial numbers. Identical in every way.
13 You fill out one, the pilot; you mail the other to a
14 cooperative, or transmit the other to a cooperative sib-
15 ling by whatever means are available.

16 then
16 DR. HODDER: -- so, you left the selection of
17 which sibling to send it to up to the pilot?

18 DR. ROAN: Yes. That is right.

19 DR. HODDER: That, of course, raises some ques-
20 tion of bias. The question that I am interested
21 in is: are you looking into the people who do not respond
22 -- and is this going to be a one-pass procedure? Are
23 you going to look at the population that did not respond
24 and see in a small subset, at least, if they are sub-
25 stantially different from the responders?

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1 DR. ROAN: We could do that.

2 DR. HODDER: With this high a non-response
3 rate, I think you either have to do that, or you really
4 can't generalize except to the people that you specifically
5 questioned.

6 DR. ROAN: That is true, but here, again, remem-
7 ber we have -- you respond or you don't respond. I have
8 absolutely no control over you. Some of them got busy
9 and just didn't get around to it. I am part of a respira-
10 tory disease study started by the University of Arizona;
11 I am a scientist of some sort. I haven't been filling out
12 the damn thing for the last couple of years. I don't know
13 of any good reason why I haven't except everybody wants
14 to fill out forms. And these people are just like any one
15 of you. There are some potential biases in here. That is
16 recognized, except for this, and I will defend this popula-
17 tion strongly on that. They are equally concerned. I
18 have no reason to suspect that they are suppressing it.

19 I will give you an example of one pilot. I
20 couldn't give you names of people, but there was one pilot
21 that had one hell of a job figuring out what sibling.
22 He had 19 brothers and sisters.

23 (Laughter.)

24 DR. MOSES: What did you do about other children?

25 DR. ROAN: They dropped out. Just for the bene-

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1 fit of the women in the audience that poor mother
2 experienced 17 pregnancies. She had three sets of twins.
3 I do remember, because it was so outstanding, the form
4 listed: mother's health is fine. This is not the pilot;
5 this is the pilot's mother. The father's health: fair.

6 (Laughter.)

7 DR. HODDER: The reason I bring that up is that
8 if you allow the pilot to choose which of the siblings --

9 DR. ROAN: Yes.

10 DR. HODDER: -- for example, I could see him in
11 a sensitive situation, he may choose not to send that
12 questionnaire to someone who just had a miscarriage rather
13 than bring that question up to them. So, I think to
14 prevent bias in that situation, you really have to sample
15 the sibling --

16 MR. COLLINS: I would like to say, Dr. Hodder,
17 that our members are intelligent enough to have thought of
18 that. With regard to this kind of a survey, I suspect
19 that their concern over pesticide exposure would overrule
20 any thoughts they might give to some deception in the
21 handling of the forms.

22 We, at our next Board meeting, however, are going
23 to solicit the membership again to reinitiate those persons
24 who did not yet participate primarily at the suggestion of
25 Dr. Matanoski who would like to see a higher population

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1 study.

2 DR. HODDER: I would agree with you up to a point.
3 The problem ^{that} is/when you have less than ^a 50 percent
4 response rate, it is hard to say that there are no factors
5 that make people not send things in.

6 MR. COLLINS: There may have been. This is all
7 we could get.

8 DR. ROAN: I know of no study where you get a
9 response rate of much above 30 percent voluntarily when
10 you mail out questionnaires.

11 DR. MOSES: I would just like to respond to that.

12 Many of the acetic gas studies that were done had
13 quite much higher. There were some problems in the control
14 population didn't get as good response --

15 DR. ROAN: That's right.

16 DR. MOSES: -- because as I noticed in yours
17 you had an 18 percent response from your sibs and a 32
18 percent response. Assuming 1,200 went out to each one
19 and a 32 percent response from the pilots themselves --

20 DR. ROAN: Yes.

21 DR. MOSES: --or whoever the initial people
22 were. Some of these went as high as 80, 85 percent, and
23 even those are not -- you would really like to see it
24 better, but there was an effort made -- and I think this
25 is extraordinarily important and I would like to support

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1 Dr. Hodder's point, that you really must know who those
2 people are and why they didn't respond, because they
3 may be very different in many ways from the people that
4 did respond.

5 I would -- incidentally, I hope Dr. Erickson is
6 going to make some response to this since this is his area
7 I would very much like to know what his impressions are if
8 he doesn't mind giving them.

9 DR. ERICKSON: I'm afraid that the presentation
10 has been brief enough that I am confused. I don't
11 understand all of the procedures which were used in forming
12 matched pairs here and there and they seem to vary in
13 number, and I just don't feel that there are enough details
14 presented for me to make any evaluation of it at the
15 moment, and in order to help make that evaluation, I
16 think it would be very useful if you could provide us with
17 the questionnaires that were used.

18 DR. ROAN: You have them.

19 DR. ERICKSON: No, we don't.

20 MR. COLLINS: They have neither the questionnaire
21 nor the list of the consulting group.

22 DR. ROAN: We can provide you with the question-
23 naire. In fact, I have overhead projection if you
24 want to go through it.

25 DR. ERICKSON: Pardon me?

1 DR. ROAN: I have slides of each page -- it's
2 a 16-page questionnaire; it is quite detailed.

3 I can make them available.

4 DR. SHEPARD: What I would like to do, as we
5 have with other reports of this nature, is to ask that they
6 circulate the reports and all information relating to the
7 reports to members of the Committee and ask for their
8 comments, the whole Committee, and maybe I will ask
9 specific questions from specific members, depending on
10 their expertise and then make this report -- this consensus
11 or grouping of responses available to the Committee as a
12 whole and to the Association, because as you indicated in
13 your preliminary remarks, you would welcome such comments --

14 MR. COLLINS: We certainly would.

15 DR. SHEPARD: -- and we would like to stay in
16 touch with you and keep abreast of your on-going efforts.

17 MR. COLLINS: Thank you.

18 DR. SHEPARD: Any other questions to these
19 gentlemen before we go on?

20 (No response.)

21 DR. SHEPARD: Thank you very much. I really
22 appreciate your coming and sharing your data with us.

23 And with us is a distinguished foreign guest,
24 Dr. Giuseppe Reggiani, who comes from the Hoffman-La Roche
25 Company based in Basel, Switzerland. Dr. Reggiani has

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1 been working very closely with the Seveso episode and we
2 are very fortunate in having him with us today to give
3 us an update on the data that has emanated from that
4 incident.

5 Dr. Reggiani.

6 UPDATE ON THE SEVESO EXPERIENCE

7 DR. REGGIANI: Thank you very much, Dr. Shepard
8 and may I say, first of all, that I am very pleased to be
9 here and would like just to express my gratitude to you,
10 Dr. Shepard, and to the Veterans Administration for the
11 kind invitation.

12 It is, in fact, an honor and a privilege for me
13 to speak to many people that I know well and that I respect
14 and admire, not only because of their professional skill
15 and competence, but, first of all, for the honesty of
16 their minds.

17 I am very sympathetic with the problems that
18 you are facing here in the United States, Dr. Shepard,
19 and the Veterans Administration at large, because it is
20 very, very close to the experience that I have had my-
21 self after the accident in Italy. The problems that
22 2.5 million veterans, I believe, and their families and
23 relatives live under the same psychological stress
24 that has been experienced by the citizen population after
25 the accident in July '76, with a difference that now that

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1 population has seen what happened during these five years,
2 at least for the acute phase or short-term phase of
3 possible health effects, but that, unfortunately, cannot be
4 applied today for the Vietnam veterans, not yet.

5 I assume that you expect me to offer to them
6 some information which would be able to relieve that kind
7 of anxiety, that kind of tension, and I hope that I would
8 succeed.

9 I consider myself an expert in relieving anxiety
10 and tension because in the early '60s, I developed
11 with the clinical trials, Librium and Valium and have been
12 successful in their purpose.

13 (Laughter.)

14 DR. REGGIANI: Now, let's hope for the best.

15 Now, first of all, the source of my data, which
16 I will present here today to you, will be just a few
17 highlights because the amount of data is very large.

18 The source of the data are, first of all,
19 the reports of the medical commissions in Italy, locally
20 in the region where the pollution is located and our
21 medical commissions or scientific advisor commission to
22 the Italian government -- it is their reports upon which / I am basing my
23 data today, and they are updated up to November 9, 1980.

24 The second source is my discussion

25 with the members of these commissions in Rome

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1 and in Milan and
2 discussions that I had last October in Rome and recently
3 at the beginning -- the middle of January with Dr. Marcus
4 Klimber. Dr. Klimber is the chairman of the

5 International Steering Committee, the committee which is
6 in charge of monitoring, guiding, suggesting -- making
7 suggestions to medical commissions in Italy.

8 I believe that it is not necessary for me just
9 to enter into the question of the environmental situation
10 there. I have given the most recent publications to
11 Dr. Kearney and Mr. DeYoung, and if you want to have copies
12 of them, I can provide that. In these documents
13 you will find that the analysis of the soil, of the
14 vegetation, of the water, of the air, of the biological
15 material has been followed up during these years and that
16 in part of Seveso there is still a certain amount of
17 TCDD.

18 The amount of TCDD, as I assume it is already
19 known to you, but I would be glad just to show -- I believe
20 that is just the amount which has been
21 calculated during the months which have followed the
22 accident. You can see that there is a total of about
23 600 gram of TCDD which have been found between the parts
24 which has fallen on the soil, or which has been absorbed
25 by the vegetation and the part which is still in the

1 rafters, or on the roof of the factory, and that's just
2 -- I don't need just to enter into the methodology of the
3 analysis, I assume that you believe that it is 2,3,7,8-
4 TCDD and not any other isomers.

5 Now, the second aspect is the question of the
6 exposure or, first of all, the classes of the populations
7 -- or the populations which has been exposed. Depending
8 on the content of concentration of TCDD in the soil,
9 they had been divided ^{into} / three zones
10 three zones of different exposures
11 selected for the medical
12 health survey.

13 The first part, there are a group of 730/^{people}
14 of Zone A with the highest concentration, 245 micrograms
15 per square meter, which have been exposed
16 during the first two weeks. That can be considered the
17 population acutely exposed and which had been
18 evacuated.

19 A part of that population, about 450 people,
20 returned to the zone -- to the part of the Zone
21 A which had been decontaminated about 1 1/2 years later.

22 They can be added to the second group, the group of
23 the Zone B where the average concentration of TCDD in the
24 soil is 3 micrograms per square meter, where the total is
25 about 5,000 people.

1 And then there is Zone R where there are only
2 scattered parts which contain very low
3 quantities of TCDD and where there is a large population.

4 And then as in matching populations for the
5 purpose of examining the health conditions of these
6 populations during these years and other communities out-
7 side around these core -- central core have been added to
8 that for a total of 220,000 people.

9 Now, let's go back to the classes which have
10 been examined closely. That means, for instance, the Zone
11 A people, the people in the Zone B, which means those which
12 certainly had the opportunity to have risk of exposures.

13 How was it controlled? How many
14 have been kept under control during these five years.
15 For the Zone A, in particularly, almost 100 percent have
16 been followed up and they are still under control.

17 For the Zone B, a part of that has been
18 controlled up to 100 percent, for instance, the children
19 between the ages -- the school children between the ages
20 of 6 and 14. And they are still under control.

21 Then the plant workers of the Emazo
22 factory, 160 people. They have been under control during these
23 five years without any loss at all.

24 The decontaminators, for instance, those people
25 working in the soil of Zone A, 40 decontaminations of

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1 the soil of the gardens, of the houses for a total of
2 about 800 people. They have always been kept under close
3 control 100 percent.

4 The military personnel in charge of just keeping
5 guard around the Zone A which is still today fenced in,
6 which is just behind fences.

7 Then all pregnant women of Zone A, B and R.
8 All newborns of these three zones. All hospitalized cases,
9 of course, coming from these zones, and all death cases,
10 not only for those three zones, but for the whole territory.

11 Just to give you in respect of the 5,000 people
12 of Zone B, how many are not compulsions to present
13 themselves they had just to volunteer and in respect
14 of the laboratory data, the chemists -- the serum chemistry,
15 for instance, blood examinations, and so on, urine
16 analysis about 80 to 82 percent have volunteered and have
17 been examined at different stages.

18 During these five years, with the of course, passing
19 the time, the interest or the eagerness to volunteer
20 for that type of examinations decreased because
21 people realize that they were in good health.

22 Now, can we say that these populations have been
23 exposed to TCDD? What evidence have we to show,
24 in effect, that they have been exposed and have absorbed
25 TCDD? Yes, we have some evidence for that. One case

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1 that's a woman who died in February of '77. She was in
2 the Zone A close to the factory, certainly in the part of
3 the Zone A with the highest concentration contamination
4 of TCDD. She remained there during two weeks and she
5 was evacuated. She was hospitalized in the beginning of
6 October of the same year for phlebitis. Then in the
7 hospital after two weeks she developed a jaundice. From
8 the jaundice, it was discovered that she had a tumor of
9 the liver. In fact, it was not of the liver; it was of
10 the pancreas and she died in February of '77.

11 Fortunately for us, the tissues have been
12 preserved and have been analyzed. They have been analyzed,
13 first of all, in Italy, but unfortunately, the limit of
14 detection was insufficient. It was 250 ppb and, therefore,
15 they have been sent to the UK, and that is just the concentra-
16 tion which has been found.

17 The total for the body was 40 micrograms. Keep
18 in mind, February '77. If we would assume, for instance,
19 a half life for TCDD for the human being of two months,
20 this person, this woman would have had at the beginning,
21 at the moment of the highest exposure, about 280 micrograms
22 of TCDD in her body, about 5 microgram per kilogram.

23 Another example, breast milk, the breast milk
24 obtained from women of the Zone A has been sent to Harvard
25 to Dr. Masselson, to Dow, and to Dr. McKinney

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1 at the National Institute of Environmental Health and
2 Sciences in North Carolina, that is, just the results
3 of the three samples. Dr. Masselson is the one who says
4 that his limits of detection is 1 ppt.

5 The National Institute says it is between 2 and
6 5. Anyway, we have at least other hints that, in fact,
7 these populations has been exposed and has absorbed TCDD.

8 Another example, yes, now moving up to the
9 clinical --

10 DR. SHEPARD: Dr. Reggiani, were these samples
11 taken from those numbers of different individuals?

12 DR. REGGIANI: They are code numbers. There
13 are three different samples.

14 DR. SHEPARD: Oh, I see.

15 DR. REGGIANI: They are three different samples,
16 code numbers and out of that, that code numbers, they have
17 been sent to Dr. Masselson and to Dr. John Moore in
18 North Carolina.

19 DR. SHEPARD: Thank you.

20 DR. REGGIANI: And to Dow, of course.

21 Now, another example, another evidence that the
22 population has been exposed, in my eyes at least, chlor-
23 acne. This is what happens between '76 until today. In
24 fact, just now, by the middle of February, the latest
25 screening of the children which is just running now will

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1 be ended. And you can see that the adult populations of
2 Zone A and B, and part of Zone R, as well as all the
3 children of the zones with the highest TCDD in the
4 environment have been examined and a certain number of
5 them have developed chloracne.

6 And it is possible -- and Dr. Suskind,
7 will support me saying that that's an evidence of
8 exposure to TCDD.

9 Now, let's see whether there is any correspon-
10 dence, any correlation with the level of exposure.

11 You can see in this table where you have the
12 frequency of chloracne for the children living in Zone A;
13 for those living in the Zone B, and for those living in
14 Zone R. You will see that the highest frequency is

15 at the zone where you have the highest contamina-
16 tion. That means, the children who had the opportunity
17 to get in contact with the highest concentration of TCDD.
18 Now, what happens -- now, I'm moving on to the clinical
19 part just to give you the situation as it is today.

20 What happened to these children? You can see
21 that from ^{the} table here that the grading intensity of the
22 disease of chloracne, it is just a shift from the highest
23 number five with the highest most severe aspects of chlor-
24 acne to the complete disappearance, healing of that in
25 '79 and practically today there is no more new cases which

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1 which have appeared.

2 I consider that these three items are just
3 the evidence that this population has been exposed to
4 TCDD and has absorbed TCDD.

5 Now, the other parameters -- the other health
6 parameters which have been examined in this population,
7 I will take the liberty to do it last, because it is the
8 most difficult to explain.

9 Let's move to the nervous -- peripheral nervous
10 system. In the peripheral nervous system, there are
11 practically no clinical signs of any effect on the peripheral
12 nervous systems, but they have been revealed in some cases
13 if specific methods of detection have been used. In that
14 case, I'll just give you an example of the examinations of
15 the peripheral nervous systems with the measure of the
16 conduction velocity. In that case, the motor conduction
17 velocity -- both motor and sensory conduction velocity
18 has been examined.

19 There are just two populations, one is just the
20 Zone A, 414 people and the region is just one community,
21 which is one part of the 11 which are under health
22 survey and you will see they have found at that moment;
23 9,077 no differences.

24 If you have to consider that that is a rather
25 highly industrialized territory where you have a lot of

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1 chemicals in the environment. Many of them are chlorinated
2 chemicals. TCDD is not the only one. Therefore, the
3 medical commissions in Milan decides to do a different
4 kind of approach to the question of the neuropathy or
5 the possible neurological effect in a different way.

6 They have changed the populations. They have
7 taken one group of the Zone A, 277, and then they
8 have taken a certain unexposed control group about 100
9 miles away, just living in a small village on a lake peace-
10 ful place where there is no pollution, no contaminations,
11 no chlorinated chemicals in the surrounding.

12 And then you can see that there are no differ-
13 ences practically, at least, not in the neuropathy of
14 known etiology and not in the neuropathy of unknown
15 etiology, not for what can be considered the clinical
16 science of neuropathy. There are differences in the
17 symptomology that can be explained by the fact that the
18 populations living in the zone was, of course, to a
19 certain extent primed with the idea of having something.
20 The other was completely unaware of anything.

21 But then if you examined them closer and taking
22 some samples or individuals of these populations which
23 have not only neurological symptoms, but also either signs
24 of liver impairment or chloracne, then there is higher
25 frequency in Zone A.

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1 Whether this chloracne was of TCDD origin, or
2 of other chemicals, is not known because during these
3 studies the dermatologists have found something which they
4 were not aware of, that's that chloracne in industrialized
5 zone has a baseline of about 0.1 to 3 percent of the
6 whole population.

7 DR. SUSKIND: Were the nerve conduction velocity
8 studies also done in this comparison?

9 DR. REGGIANI: Yes.

10 DR. SUSKIND: That's not listed; is it?

11 DR. MOSES: Is that what neurological syndrome
12 means?

13 DR. SUSKIND: The nerve conduction velocity.

14 DR. REGGIANI: Oh, I'm sorry. In this case,
15 it has not been done.

16 DR. SUSKIND: So, you are just really comparing
17 neurological syndrome --

18 DR. REGGIANI: Only syndromes, yes.

19 DR. SUSKIND: -- with people having liver
20 problems --

21 DR. REGGIANI: Yes.

22 DR. SUSKIND: -- chloracne as compared to the
23 control?

24 DR. REGGIANI: Excluding under the liver problems
25 all those drinking wine; all those having other problems

1 with the liver, all that.

2 DR. KOLBYE: I just wanted to ask on the liver
3 impairment, could you explain a little bit more how that
4 is defined? Is that enzymatic
5 abnormalites, or what?

6 DR. REGGIANI: It is only based on the serum
7 chemistries, and only based practically on three or four
8 analyses the two transaminases, alkaline phosphatase
9 gamma GT.

10 DR. KOLBYE: Thank you.

11 DR. REGGIANI: When can we
12 decide that it is a liver impairment and when can we decide
13 that it is only compensation in the function?

14 I have heard many opinions on that. Some
15 pathologists, specialist tells me that the liver can be
16 considered damaged only if the normal values, the standard
17 values is at least three times higher. In between the
18 standard value and the highest values, three times the
19 standard, that is only in effect a compensatory effect ...
20 of the organs trying to eliminate it, to metabolize it,
21 just to do something with it.

22 But, I repeat, it is just a question of opinion,
23 I am just repeating.

24 In these cases, they were considered a liver
25 impairment, but they had not very high values in their

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1 functions.

2 DR. KOLBYE: Thank you for that clarification.

3 DR. REGGIANI: Now, let's go on now to
4 another aspect --

5 DR. MOSES: Excuse me.

6 DR. REGGIANI: Yes?

7 DR. MOSES: Dr. Reggiani, are you going to show
8 us any more on nerve conduction velocity? I am familiar
9 with Dr. Balari's work in which I think some
10 evidence of abnormal nerve conduction velocities were found,
11 if my reading of those papers is correct?

12 DR. REGGIANI: Dr. Moses, I could keep on show-
13 ing you a lot of data, then I would be here tonight and
14 Dr. Shepard told me that at 12:00 o'clock we have to
15 adjourn because the meeting room has been --

16 DR. MOSES: Well, but I think that it is
17 important that the group know that there are some reports
18 from Seveso, and I am mentioning Dr. Balari's work, in
19 particular, in which nerve conduction abnormalities
20 apparently have been found, or there is a question about
21 whether or not there may be some nerve conduction abnormal-
22 ities in Seveso, the Zone A people, as compared to another
23 group of people who didn't have the dioxin exposure.

24 DR. REGGIANI: Yes. Yes, I'm aware of that.
25 He has just found that. If you want, I can give you then

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1 the details of that study?

2 DR. MOSES: -- well, that is up to the group.
3 I just was mentioning it as being something that has been
4 reported.

5 DR. REGGIANI: Yes.

6 DR. REGGIANI: But, again, they were just the
7 same two populations. Just the same two populations which
8 I have here. One which is living far away, certainly not
9 exposed to any chlorinated chemicals, and one, on the
10 contrary, living there in that surrounding.

11 I don't need to say -- it is not that I do
12 not believe the method of study. I have been told that if
13 you repeat the examinations twice in the same day, you
14 will have two values just in the same day.

15 I don't want to discredit the approach
16 or the methods of study the peripheral nervous system; I
17 am only saying that it is probably not the only method to
18 detect an effect.

19 Now, if you don't mind, I'm trying just to keep
20 my time.

21 Again, the rate of malformation, the
22 birth effects have been a problem because the people there,
23 the medical commissions have been confronted with the
24 usual problems which you have in birth defects. The birth
25 defects which have to be notified are, by law, always

1 just a limited number of, or perhaps only one class of
2 all birth defects. Therefore the frequency in the popula-
3 tion is always very low. In Italy, in that part, for
4 instance, where they have to notify for the law only the
5 practical -- the hip dislocations that they had occurred,
6 the frequency of .05 per 1,000.

7 Now, at the moment the chart just includes other
8 types of birth defects. Immediately, the frequency, the
9 rate increased and since the populations, and, of course,
10 the doctors there in charge at that time of the study,
11 became aware of the problem more and more with the passing
12 of time, with passing of the years, the number has
13 steadily increased. Today, we have a much larger frequency
14 a larger rate than it is been found in the past. That
15 does not mean that in the past the same rate was not
16 present. It was not detected.

17 But what is important is that during the period
18 for instance, in Zone A, the pregnant women have been
19 exposed to the highest concentrations of TCDD between
20 '76 July until the end of '78, Zone A and Zone B.

21 By pure chance, all the newborns of these women
22 were normal. I believe the total is 104 and one would
23 expect that at least two or three of them to have some
24 malformation, some major malformations. Perhaps seven or
25 eight, if you want just to include the minor malformations.

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1 but they hadn't.

2 I'm just keeping the situation as it is today.

3 The frequency of
4 abortion has been a problem, too, and it still remains a
5 problem.

6 If we take the frequency of abortion for the
7 whole population, dividing, of course, between the amount
8 of the communities with the highest part of the territory
9 contaminated, 50 percent which is the first line over there,
10 and the other two communities with only 20 percent of
11 the territory contaminated. And then we compare that
12 with the frequency of abortions with the seven townships
13 which are outside the contaminated zone, and we relate that
14 to the frequency of the province of Milan,

15 then we don't see any difference in the course of
16 the years, certainly not in '76, '77, '78. Still today
17 there is no difference.

18 But, of course, these values, or this kind of
19 frequency is diluted in the whole population. And perhaps
20 only a few women have been affected and have had
21 abortions because of TCDD. If you put that all together.
22 in the whole group, this small number will disappear.

23 Yes, that is the way it has been for the
24 time between '76, immediately after the accident, the
25 third quarter and the fourth quarter and for the 1977, and

1 I don't have here the last values for the last quarter of
2 '77, but they are unchanged. There is, in fact, a fluctua-
3 tion in the frequency of abortions in that period where
4 certainly there was the highest risk of the contamination.
5 But, again, there is no difference between just the parts
6 of the territory divided in relations to the contamination
7 -- the amount of contamination.

8 Now, I will skip the part concerning the immune
9 capability and the chromosome irregularity because in
10 respect of the immune capability something strange happened
11 and that is that children with and without chloracne,
12 which have been examined six times during these five years
13 have some parameters, for instance, for the analytic
14 activity of the complement, they had an increase in six
15 out of six examinations. They had an increased mitogenic
16 response in three out of six examinations.

17 And they had an increased number of peripheral
18 blood lymphocytes in two out of six examinations.

19 Everybody is at loss just to try to give an
20 interpretation to these values, and it the recommendation
21 of the International Steering Committee where, by the way,
22 Dr. Selikoff is on the International Steering
23 Committee, and he was there in January, and they have
24 recommended that the study of immune capability should be
25 carried on.

1 Now, for the chromosome analysis, no differences
2 have been found in different groups which have been
3 examined.

4 Now, let's go to the liver functions. I have
5 already given you an idea of the problems of how to
6 interpret the story of the liver function.

7 There is, I believe, about 245,000 analyses which have been
8 stored in the computer for these populations for about
9 22 different analyses, and among them, of course, the
10 transaminases, the gamma GT and the alkaline phosphatase

11 In fact, there have been continuously
12 fluctuations in these. At the beginning, many of these
13 cases where they had some increase, had an
14 enlargement of the liver, which then later disappeared.
15 But all that did not help very much. None of these people
16 developed jaundice, except what you can find, as usual,
17 in particular populations. Therefore, one
18 member of the International Steering Committee, Dr.
19 Donald Young, who, I believe, is the head of the Central
20 Laboratory of the Mayo Clinic recommended abandonment of
21 that type of approach, to change that and to use a new
22 approach which I will show you.

23 He recommends these four analyses --
24 abnormal liver functions should be based on these four
25 analysis: alkaline phosphatase, aspartase transferase,

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1 alanine aminotransferase and gamma GT.

2 Now, what happens if these values are not normal?

3 Well, if they are, all of them, all four aren't normal,
4 then people have to be followed up. That is if they/ ^{are} only
5 partly -- some of them are normal, but have just to be
6 repeated and see what happens.

7 If they all four become normal, then we will
8 have to follow-up. If they are only some of them, or one
9 of them are abnormal occasionally, then they--
10 should be ignored.

11 I have no comments on that kind of approach.
12 Perhaps, you to tell me how to interpret
13 these new approaches.

14 Up to now, I believe about 70 cases have been
15 found with all four analysis abnormal, which then will be
16 followed.

17 Another analysis, which was interesting can be
18 applied, of course, only for the children is the analysis
19 of the urinary -- the (inaudible)
20 as a sign of liver enzymes activity. And, in fact,
21 they are higher in these regions for the children with
22 chloracne than for the others. So, that is a new aspect
23 which will probably be considered.

24 In other words, we are going away from the
25 pure pathology, clinical pathology and moving to a more

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1 sophisticated examinations where sub-clinical signs are
2 considered.

3 Another aspect which has been examined is, of
4 course, the porphyrin in the urine. It has been said
5 that in cases with severe exposure to TCDD in the past
6 accidents in the industry have developed porphyruria

7 --

8 Now, again, the eliminations in the urine have
9 been examined on several occasions in the populations
10 that I have mentioned, but, again, there have been fluctua-
11 tions. The value which is considered to be just the
12 ceiling of 200 micrograms per liter have reached sometimes
13 more than that, but by and large it remained always just
14 in that --

15 Only two cases have developed porphyruria --
16 a man of 24 years, living in Zone B, a man of 24 years
17 and his sister of 20 years.

18 And Dr. Sisk has examined these
19 cases -- not only, he has examined all the members of the
20 same family and the relatives living far away from
21 Switzerland. That, in fact, he has presented these cases
22 in Rome during the symposium. In fact, they are members
23 of a family with a genetic error of metabolism.

24 These cases have been -- these two, man and
25 woman has been treated with edroxy chloroquin

1 two tablets per week for about four months and all signs
2 have disappeared today.

3 Now, what happens now beside all that?

4 I have already mentioned that the whole popula-
5 tion, the mortality and the morbidity of all populations
6 under survey, one way is dividing by zone of intensity
7 of contaminations, as I showed in the beginning. We have
8 already some data about the death statistics of the
9 Seveso region for the total death rate, for the cancer
10 death rate, and, of course, it is too soon to be meaningful.
11 And for the cardiovascular mortality, there is differences
12 for these five years. And all that will continue and the
13 follow-up is meant to be carried on for at least for 20
14 years.

15 And that is the end of what I intended to present
16 to you.

17 Thank you.

18 DR. SHEPARD: Thank you very much, Dr. Reggiani.
19 It is very interesting data and I am sure it was frustrating
20 to you as it is to us not to be able to devote more time
21 to this, but as time goes on, I hope we can stay in touch
22 and be kept abreast of the data as it develops.

23 Are there any quick questions of Dr. Reggiani?

24 Yes, Dr. Suskind?

25 DR. SUSKIND: This is an enormous source of

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1 excellent information and one of the things that you
2 indicated was that there are -- you're conducting studies
3 of decontamination workers.

4 DR. REGGIANI: Yes.

5 DR. SUSKIND: So that you have baseline pre-
6 exposure information?

7 DR. REGGIANI: Exactly.

8 Yes, that is right.

9 DR. SUSKIND: How far along is that?

10 You say there are 800 --

11 DR. REGGIANI: The moment that they are enlisted,
12 they are, of course, examined clinically. The history
13 -- clinical history is taken.

14 DR. SUSKIND: How long have they been followed
15 so far? A year, two years, three years?

16 DR. REGGIANI: Since they have started. Not
17 only that, there are always new groups getting in and
18 coming out. The first group entered the Zone A for
19 decontamination of the Zone A 7, -- 6 and 7, the lowest
20 contaminations already at the end of December '76. They
21 worked there until May '77. Then later on in October,
22 the people came back again. Then our group of decontamina-
23 tors entered our part of the Zone B and now they are
24 working in the Zone A with the highest contamination.
25 And all of those are still kept under control.

1 DR. SUSKIND: What I am asking though is that
2 those early decontaminators, were they examined before
3 they went in?

4 DR. REGGIANI: Yes. Oh, yes, of course.
5 They had to be admitted. If they had some evidence of
6 disease, and so on, they were excluded.

7 DR. KEARNEY: Weren't many of the decontamina-
8 tors members of the Italian Army?

9 DR. REGGIANI: No, none of them were members of
10 the Italian Army.

11 DR. KEARNEY: I thought they were.

12 DR. REGGIANI: No. They are members of the
13 agencies, special agencies that do that kind of cleaning
14 procedures.

15 DR. SHEPARD: Thank you very much, Dr. Reggiani,
16 we really appreciate your taking the time to be with us.

17 I'd like now to ask -- we are again going to
18 deviate from the printed agenda for a moment and ask Dr.
19 Erickson to bring us up to date on his experiences on the
20 CDC study.

21 STATUS OF CDC BIRTH DEFECTS STUDY

22 DR. ERICKSON: As most of you know, CDC is in
23 the beginning stages of doing a case control study to
24 try to determine whether Vietnam veterans are at some
25 increased risk siring babies with birth defects.

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1 Study cases will be babies who were born with
2 congenital malformations in the metropolitan Atlanta --

3 DR. SHEPARD: Excuse me, could you get a little
4 closer to the microphone.

5 DR. ERICKSON: -- the study cases will be babies
6 who were born with congenital malformations in the Atlanta
7 area over the past decade and who have been registered
8 in the Center for Disease Controls Congenital Defects
9 Surveillance Program. Study controls will be normal
10 children who will be ascertained through the State of
11 Georgia Vital Records system.

12 Basic study procedure will be to locate the
13 parents of these case and control babies, interview all
14 available willing mothers and fathers of these babies --
15 asking them about a wide variety of risk factors which
16 may be associated with the occurrence of birth defects
17 and including fairly extensive questioning about service
18 in Vietnam for men who were identified as being Vietnam
19 veterans.

20 The protocol which we developed has had a
21 rather extensive review. It underwent a special in-house
22 scientific review at CDC. We brought in a panel of
23 university based scientists to review it. It had a review
24 by the Interagency Work Group on Phenoxy Herbicides.
25 Four veterans groups were given the opportunity to review

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1 it. At the moment, it is undergoing final review
2 at the Office of Management and Budget. We expect final
3 clearance from them sometime this month.

4 We have had a rather major change in procedure.
5 It was decided early in November that rather than hire the
6 people who will be doing the interviews -- rather than
7 hiring people to work directly for CDC, that CDC would
8 contract with a private concern to do the interviews.
9 CDC will retain all scientific direction and do the analysis
10 of the data and the final reporting.

11 Specifically, what we will do is contract out
12 for the tracing of the parents of the cases in controls
13 and the conduct of the interviews.

14 We are just about to release a request for
15 proposal and expect to get responses from prospective
16 contractors sometime in the spring to finally release
17 -- finally award a contract at the end of summer -- late
18 summer of this year. We expect to begin a pilot study in August or
19 September, to begin a full study in December or January
20 of next year, and to

21 have a final analysis and report ready,
22 hopeful, sometime around the end of 1983.

23 I think that about sums up the major points.
24 We have been very busy with this, but it is all rather
25 mundane housekeeping chores that we need to do to get the

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1 study rolling.

2 DR. SHEPARD: Thank you very much, Dr. Erickson.

3 Are there any questions of Dr. Erickson?

4 DR. MOSES: Yes. I was wondering how many
5 babies are in that 10-year period?

6 DR. ERICKSON: Well, we ^{now} have cases of
7 babies on file from 1968 through the present -- or
8 babies born between 1968 and through the end of 1980, which
9 was the target time period. We had somewhere between
10 12,000 and 13,000 babies. Not all of those babies will be
11 study babies.

12 DR. MOSES: How many will? Do you have any idea?

13 DR. ERICKSON: Roughly around 7,000 study babies
14 who are cases. We have approximately 3,000 normal babies
15 and the families participating in this control.

16 DR. SHEPARD: Any other questions?

17 DR. MOSES: Can I ask Dr. Erickson another
18 question?

19 DR. SHEPARD: Sure.

20 DR. MOSES: This is specifically for the Atlanta
21 area, as I understand it?

22 DR. ERICKSON: Yes.

23 DR. ERICKSON: Is CDC going to be doing anything
24 else nationwide regarding this? I'm sure that was thought
25 about.

1 DR. ERICKSON: Yes, right.

2 CDC has been collecting data on babies born with
3 birth defects in the metro Atlanta area since '68. We
4 do collect data nationally and have been doing it since
5 1970. It is very difficult for us to get certain kinds
6 of information in our national study. The registry we have
7 of the Atlanta babies is very complete-- a very complete
8 ascertainment of babies with birth defects. The
9 kinds of information that we are able to gather is also
10 rather extensive because we have our own
11 people visiting the hospitals in the Atlanta area.

12 They are extracting the kinds of information
13 that we want from hospital charts.

14 So, that, for example, we have full names of
15 the mothers and fathers and their addresses at the times
16 of births and telephone numbers, and things like that
17 on file.

18 We do not have that sort of information available
19 on a national scale, nor is there so far as I am aware,
20 any registry similar to our metro Atlanta registry
21 which would allow you to have a starting point for a case
22 control study, at least not a relatively easy start.

23 DR. MOSES: Thank you.

24 DR. IREY: How many cases did you say you had
25 of --

1 DR. ERICKSON: Well, there are somewhere between
2 12,000 and 13,000 babies in our file out of a
3 population of roughly 300,000 births.

4 DR. IREY: Yes

5 DR. ERICKSON: Now, a lot of these babies have
6 what we would call minor defects or minor developmental
7 anomalies which we do not intend to study. We were taking
8 what we class major malformations and that amounts to
9 somewhere between 7,000 and 8,000 babies. Major malforma-
10 tions being defined as one which there is a serious life
11 threatening defect, a defect which requires substantial
12 surgery or might engender a substantial psychological
13 problem for the baby.

14 DR. SHEPARD: Thank you very much, Dr. Erickson.
15 It is very good to hear that progress is going on and
16 I am sure that we will be following this work very closely.

17 Next, I would like to call on Dr. Moses to give
18 us a little thumbnail sketch of some of her activities in
19 the Mt. Sinai group.

20 CLINICAL RESEARCH AT ENVIRONMENTAL SCIENCES LABORATORY

21 DR. MOSES: I am from Mt. Sinai, from the
22 Environmental Sciences Laboratory, and we have
23 done a fair amount of work in this area. We
24 studied workers who have been involved in / the manufacture
25 of 2,4,5-T in one instance. These are Monsanto Chemical

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1 Company workers in Nitro, West Virginia. And we have
2 also studied another group of workers involved in the
3 manufacture of 2,4,5-T and 2,4-D, and these are Vertac

4 Chemical Company workers in Jacksonville,
5 Arkansas.

6 Before I give you any information at all, I want
7 to make very, very clear to everybody here that we did not
8 study cancer; we did not study birth defects. What we did
9 was a current health status evaluation of worker populations,
10 both retired and active workers at these two particular
11 industrial sites.

12 The only reason I want to say that is that many
13 people think that ^{by} ^{such} ~~doing~~ studies -- we did a morbidity
14 study -- that we are going to be able to provide answers
15 about some of the birth defect and the cancer information.
16 The type of study we did does not lend itself to ^{such} answers.
17 I think we are going to have to wait for Dr. Erickson's
18 work and the mortality studies which will give the
19 answers.

20 Now, what I would like to do today is maybe
21 hold up a tiny little candle to throw a little bit of
22 light to give you some results -- some very preliminary
23 results of our investigation of the Monsanto employees.
24 And let me make clear, again, also, that this is preliminary,
25 it is limited. We do have a lot more data. We are in

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1 the process of looking at it and my hope is that within
2 the next few months we certainly will have reports on both
3 of these surveys ready for the National Institute of
4 Environmental Health Sciences who sponsored this through
5 their grant mechanism/^{which}is how these studies were paid for.

6 I think I will start with giving you some of
7 the information about Monsanto. I guess all the questions
8 will be later, but please feel free to interrupt me now
9 as we go along, if you wish.

10 Could I have the first slide, please?

11 This is just to give you some background.
12 Monsanto acquired this plant in 1929. They mostly made
13 rubber additives. They still do to this day. Over the
14 years there's been really literally hundreds of different
15 products / ^{and} intermediates and compounds and chemicals
16 that the workers at this plant have been exposed to.

17
18 It was from 1948, when they
19 started making 2,4,5-T acid, to 1969, / ^{when} they ceased
20 production.

21 Monsanto, in this facility, did not make Agent
22 Orange. They made 2,4,5-T acid, which was then shipped
23 out, esterified and mixed with the 2,4-D ester to make what
24 we know as Agent Orange. Agent Orange was not made at
25 this facility.

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1 Now, we arrived on the scene 10 years after
2 the last known production, 1979 was when we did our study.
3 This slide shows you that they used tetrachlorobenzene
4 with methanol and caustic to make trichlorophenol. It
5 was the trichlorophenol reactor where the run-away
6 reaction occurred and this was the same type of thing that
7 happened in Seveso that Dr. Reggiani was just talking about
8 except that they used ethylene glycol instead of methanol
9 which is the only basic difference.

10 shows
11 Now, this slide/the way we are analyzing the data
12 that we collected in the study. This is to give you an
13 idea of what the exposures were and what we're using for
14 a marker of exposure, which is chloracne. Now, the reason
15 we can use chloracne in this population (there are 226
16 workers that we are reporting on that are involved in
17 this analysis) is that a very high percentage of these
18 workers actually did have chloracne. The reason we know
19 it was a problem is as happens when workers have work-
20 related problems, they give it a name, and they did give
21 it a name. They called it "weed bumps," because they
22 called the chemical / they made "weed killer," and they had
23 skin problems with it.

24 Also, this was not one of the more pleasant
25 jobs there and the union negotiated for a small -- slight
addition of what they call premium pay for people who

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1 worked in this particular location with this particular
2 product.

3 Now, let me just -- this may be a little complica-
4 ted. Now, this^{slide}/is how many had chloracne to show you -- this means never,
5 past and current. What we did, we divided the people into
6 those who had never had chloracne, and that was about half
7 the people that we saw. Then there were people who had
8 had chloracne in the past, but they didn't have it now.
9 By now, I mean, on physical examination, and we did have
10 a dermatologist, Dr. Crow who came over from
11 England. He is a well known authority in this field.
12 He's an industrial dermatologist, who saw every single
13 person.

14 We also had Dr. David Bikers from
15 Case Western Reserve, who is also a dermatologist and they
16 evaluated every single person for
17 their current skin condition, and those are the people
18 that ended up in this category of having^{current} chloracne.

19 this slide shows
20 Now, what we found related to exposure.
21 We divided people into four groups. Those who had no
22 exposure to the production of 2,4,5-T (actually
23 trichlorophenol and 2,4,5-T). People who had minimal,
24 who had moderate and heavy exposure..

25 I don't have time now, but in the write-up,
we'll tell you exactly what criteria we used to put people

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1 in those categories. Then what I was very pleased to see
2 because we did these separately, the chloracne was done
3 separately from the exposure. When we put it together, we
4 found what we expected to find. The people who did not
5 have chloracne decreased as exposure increased.

6 Exposure is increasing across this way. And/or
7 you could say thing, the people who never had, but
8 currently have chloracne, there was a definite increase
9 as exposure increased.

10 And I would like to respond to something Mr.
11 Mullen said earlier that there was no relationship
12 between dioxin and disease. I don't necessarily think
13 that that's the case. There is certainly clearly a
14 relationship between exposure and chloracne. Now, what
15 exactly that relationship is, we don't really know because
16 if you see here, you will note that 24 percent of the
17 people who had heavy exposure, that's 22 people who had
18 heavy exposure, ⁱⁿ 2,4,5-T production did not get chloracne.
19 And we noticed also that we have a person over here--we
20 still can't explain that,-- who had chloracne in the
21 past. That may be related to some other industrial
22 exposure. We really don't know why that one person
23 clearly probably did have chloracne in the past, but did
24 not have it currently.

25 So, this is just to sort of set the scene.

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1 because I am going to show you some data now in which we
2 looked at -- I'm just going to give you the biochemist
3 the liver function tests and the lipids, because this is
4 something everybody is interested in. cholesterol or
5 triglycerides we know have been reported to be abnormal.

6 Liver function tests are extraordinarily
7 important and I am going to show you some frequencies of/
8 based on these groups and based on whether or not they
9 ever had chloracne.

10 If there aren't any questions, I'll go through
11 that.

12 yes, Dr. Gross?

13 DR. GROSS: In the second --

14 DR. MOSES: Here, minimal?

15 DR. GROSS: -- yes. What is missing from 100
16 percent, 64, 9 and 7 hardly adds up to 100.

17 DR. MOSES: 64, 74 -- yeah, we are missing --
18 that's probably -- it's a very good pick-up, this is
19 wrong here. It doesn't add up. The percentages seem to
20 be off. That should add up to 100 percent.

21 Thank you. I'll change that.

22 DR. SUSKIND: Marion, even though you want to
23 delay in explaining how you arrived at minimal, moderate
24 and heavy --

25 DR. MOSES: Oh, sure I can --

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1 DR. SUSKIND: -- I think it is kind of important
2 because it is critical.

3 DR. MOSES: -- sure. Okay.

4 DR. SUSKIND: And I hope you don't mind if I
5 ask some questions about --

6 DR. MOSES: No, absolutely not.

7 DR. SUSKIND: -- how this was determined.
8 Obviously since you didn't have access to work histories,
9 which wouldn't have helped you anyway --

10 DR. MOSES: Well, we did.

11 DR. SUSKIND: -- the interview was the main
12 source. What did you do with the intermittent exposure
13 people, the maintenance people? Where did you put them,
14 in minimal, moderate, heavy?

15 DR. MOSES: Okay. Let me -- okay, I'll take
16 the time because I think it is important, I will take
17 the time to tell you how people ended up in these
18 categories.

19
20 We got very, very good occupational histories.
21 We spent a lot of time. We have very skilled occupational
22 history takes, who took these histories, and we took the
23 time and we asked them -- did you work in
24 building 41? We want to know that. Or building 34 or
25 building 92 where we know production occurred.

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remembered

Some of them. But we also asked them exactly what did you do? Exactly what was your job.

Now, you are relying on people's memory. There is no question about that. People's memories, we're finding out, in taking a good occupational history, is much, much more reliable than relying on company work records because all the company work record tells you is where in terms of payroll; or in terms of getting somebody on a computer printout where they ^{were} assigned. That does not necessarily mean that's where they worked, or that is what they did. Or they may have only ^{worked} for one day, particularly in terms of the clean up after the accident. We certainly know that a lot of people ordinarily were not assigned and never had anything to do with trichlorophenol production did end up at the clean-up..

Now, if we found that out and if we know, they automatically went into this category. So, the 25 people that we saw who were in some way involved in the clean up, automatically went into the heavy exposure group.

should tell you that the company went through a lot of different changes. / ^{Production} started off in one building -- two different buildings actually and eventually / ^{the 2,4,5-T} was dried in several buildings throughout the plant. Eventually they put most of it under one roof in building 92.

1 DR. SHEPARD: Excuse me, Marion --

2 DR. MOSES: Yes.

3 DR. SHEPARD: -- you are going to have to speed
4 up a little bit.

5 DR. MOSES: Oh.

6 DR. SHEPARD: If you can just kind of give us
7 a quick overview --

8 DR. MOSES: The only way I can tell you -- the
9 only way I can tell you, explain this is to tell you
10 exactly how people were exposed to this, and then I can
11 tell you how they got into the different categories.

12 If they were involved in the drying -- if anybody
13 was in a room where it was dried, and it was dried in
14 several buildings, but they weren't actually involved
15 in the process or the manufacturing, they ended up in
16 the minimal category because they had a potential exposure
17 to 2,4,5-T. Actually, it was 2,4,5-T acid.

18 If they actually were involved in putting their
19 hands inside the autoclave and digging out the wet cake,
20 they ended up in the heavy exposure group.

21 If they worked in the lab and sometimes they
22 specimen did a / of 2,4,5-T, and sometimes they didn't, but
23 they did have direct contact with it, they ended up in
24 the moderate exposure.

25 We were very conservative where we put them.

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1 in heavy exposure category
2 Everybody that's / , really belongsthere. Anybody that
3 was involved in maintenance -- was involved in maintenance
4 in a 2,4,5-T building, ended up here.

5 Now, we just didn't say that anybody that was
6 in maintenance automatically had heavy exposure, you/always
7 didn't

8 know. It depended on when they did maintenance,
9 and if we thought it might be heavy, we put them in here.
10 But we were very, very conservative.

11 In general, I think, it shows that it probably
12 works is that we did see the relationship in which the
13 exposure categories related to the chloracne.

14 This is why I didn't want to go into it because
15 it is very complicated.

16 Yes, sir.

17 DR. PAGE: The column to your far right, that
18 would be 50 percent of those heavy exposed to trichloro-
19 phenol 10 years after they were exposed?

20 DR. MOSES: That's right. Well, it is even
21 more. I am going to show you a slide that shows --

22 DR. SHEPARD: Excuse me.

23 I am going to have to restrict questions from
24 the floor and really we are going to have to restrict
25 questions from the Committee.

26 Would you please go ahead and complete your
27 presentation

28 / . We have a whole other segment of the agenda we

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1 have to get through and there's a meeting in this room
2 at 1:00 o'clock. So, we are under a time constraint.
3 I'm sorry.

4 Go ahead.

5 DR. MOSES: Okay. What this represents here
6 is that 71 people of the 226 that we saw
7 had current evidence of chloracne. Half of the people
8 that we saw had chloracne currently, or
9 had had it at some time in the past.

10 Now, this directly answers the gentlemen's
11 question in the back. Of the people that we saw, half of
12 them had had their chloracne more than 20 years. This
13 is based on asking them how long they had had it.

14 So, it is very persistent.

15 Now, this slide -- forgive me, I don't know if
16 you can see it -- I am going to just tell you basically
17 what we found here.

18 I put cholesterol on here not because we found
19 an increased prevalence of abnormal cholesterol, but be-
20 cause people are going to want to know what we found.
21 That's the only reason it is on here.

22 SGPT and SGOT and GGT are all
23 liver function tests and are very, very important in
24 this. They are here because we did find
25 an increase prevalence of abnormalities.

1 If you will see,
2 (DEX means drinkers excluded) we took out moderate,
3 heavy and problem drinkers and that was considered to be
4 anybody that drank more than two beers a day.
5 Very fortunately, this group, were not heavy drinkers.
6 71 percent were non- drinkers or ex-drinkers.

7 Now, we didn't see anything with cholesterol.

8 We saw related to chloracne an
9 increased prevalence of abnormal triglycerides.

10
11
12 Now with SGPT, I really can't say very much
13 because the numbers are really very small, but I am going
14 to show you the means test. And the SGOT, there were no
15 abnormalities here, but there were only three people
16 abnormal in the other groups. I think the numbers are
17 really too small to say anything, but there were abnormalities.

18 GGT, when you take out the drinkers, there is
19 clearly an increased prevalence of people with an
20 abnormal GGTs in the chloracne group as opposed to the
21 group that did not have it.

1

2

3

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For triglycerides, you will see that related to exposure, there was an increased prevalence of abnormal-ities. The same it goes for / ^{SGPT} SGOT, and much, much more clearly in the heavy exposure group with GGT.

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I emphasize these are abnormals. These are above what our laboratory was and I would agree with -- I shouldn't say I would agree with, but Dr. Reggiani mentioned a three -- it must be at least a three level of increase for them to be considered abnormal.

Dr. Popper, in our laboratory, feels it should be doubled before it's considered clinically significant, which means there is liver injury. And I think that is a very important point that has to be made.

Now, we also looked at -- and I have a whole series of slides that I am not going to be showing you -- we looked at -- comparing the means, the mean differences of these tests that I showed you and many, many others. All of them, the BUN, all of it. These were the only ones that showed up being significantly different.

The means of

/ the SGPT, the SGOT and the GGT in the minimally

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heavily
versus the / exposed were significantly different.

And to get back to Dr. Suskind's question here.

The reason we use the minimal and the heavy is that we were pretty sure everybody that was in those groups belonged there. We weren't so sure about the moderates. Some of the people who were in the moderate group, we weren't sure whether they fit in the minimal or the heavy. These groups we're sure that these 45 people ^{minimally exposed} belong here and these 93 people ^{heavily exposed} -- relatively sure they belong here.

And these were found to be significantly different. That does not mean that they were abnormal though.

In terms of chloracne, the SGOT and the GGT, which are both liver function tests were shown to be significantly higher in the people who had chloracne as opposed to the people that didn't.

The triglycerides were found to be significantly higher / only in relationship to chloracne but not in relationship to exposure.

Now, I will summarize right now.

We weren't, for all sorts of reasons that we know about, able to quantify the exposure. In 1949, when this accident occurred, nobody even knew what -- that it was dioxin, or what it

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1 was that caused the chloracne.

2 Now, an effect became demonstrated in what I
3 have just shown you, is that we did^{show}/some effects or some
4 trends.

5 Now, the real question is: has injury occurred?
6 And I think on the basis of this data, we can say that
7 we really don't know. Certainly, if there is an effect,
8 it is a very minimal one, and it is possibly a statistical
9 one. And the reason I say this is because there were many
10 people -- some people in our sample with heavy exposure
11 who had had severe chloracne but at the time of our
12 examination no longer had chloracne and had normal liver
13 function tests. It is very important to make that point.

14 Now, we also found the opposite, almost any
15 combination. We did not find any abnormalities in
16 porphyrinsin the urine. And
17 none of the other tests, the BUN, etc. CBCs, we're
18 looking at those. There may be some minor changes there.
19 Nothing really significant. But basically I have shown
20 you in the biochemical parameters on our first look, and
21 we're going to be looking into this a little more of what
22 we found. And later on -- and if there isn't enough
23 time later on, during the meeting if anybody else -- I'd
24 be happy to answer anybody's questions afterwards.

25 Do I have time to take any questions if there

1 are any now?

2 DR. SHEPARD: I'm afraid not.

3 We are reserving time -- we have already run
4 out of assigned time, but we will run over a little bit
5 and have some time for questions following Major Young's
6 presentation.

7 So, we are very happy to have Major Alvin Young
8 from the Air Force who is Mr. Agent Orange.

9 ENVIRONMENTAL FATE OF TCDD

10 MAJOR YOUNG: Back 12 years ago, I would have
11 said that was a compliment --

12 (Laughter.)

13 MAJOR YOUNG: -- when I first began to work
14 with orange and dioxin. It was a very exciting time
15 to be affiliated with the program. But as the years have
16 gone by, one now doesn't know whether it is good to raise
17 your hand and say, I know all about it, because that some-
18 time doesn't attract the kind of attention you'd like to
19 have it attract.

20 I would like to explain to you a little bit
21 about the work we've done at Eglin Air Force Base. A
22 very unique situation. As Dr. Reggiani pointed out a few
23 moments ago, 260 grams, approximately, of TCDD were dissemi-
24 nated on the area of about 700 acres in Seveso, but at
25 Eglin we have a one-square mile site, that is 640 acres

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LONG-TERM FIELD STUDIES OF A RODENT POPULATION CONTINUOUSLY EXPOSED TO TCDD

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Field investigations were conducted during 1973-1978 on populations of the beach mouse, Peromyscus polionotus, from a unique 3.0 km² military test area (Test Area C-52A, Eglin AFB FL) that was sprayed with 73,000 kg 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) herbicide during the period 1962-1970. No residues of 2,4,5-T were detected at 10 parts per billion in any soil sample collected during 1971-1972. Residues of 2,3,7,8-tetrachlorodibenzop-dioxin (TCDD) were still present in 1978. During 1974-1978, 54 soil samples were collected to a depth of 15 cm on the test area. TCDD levels ranged from <10 to 1,500 parts per trillion (ppt). The median concentration was 30 ppt while the mean was 164 ppt. Liver tissue from 36 individual beachmice inhabiting the test site contained 300 to 2,900 ppt TCDD. Although a close relationship between soil and liver levels of TCDD was observed, i.e., high liver levels of TCDD were consistent with high soil levels of TCDD, bioconcentration factors (mean liver concentrations divided by mean soil concentrations) ranged from 6 for females to 18 for males. Whole body analysis of fetuses from test area females indicated apparent placental transport of TCDD. Histopathological examinations were performed of 255 adult or fetal beachmice from the test area and a control area. Examinations were performed on the heart, lungs, trachea, salivary glands, thymus, liver, kidneys, stomach, pancreas, adrenals, large and small intestine.

spleen, genital organs, bone, bone marrow, skin and brain. Initially the tissues were examined on a blind study basis. All microscopic changes were recorded including those interpreted as minor or insignificant. The tissues were then re-examined on a control versus test basis, which demonstrated that the test and control mice could not be distinguished histopathologically. The mean number of fetuses per observed pregnancy was 3.1 and 3.4 for the test area and a control area, respectively. A single female beachmouse is capable of producing litters every 26 days. At this frequency, the animals collected in 1978 may have been at least 50 generations removed from the population studies in 1973. A two-factor (treatment and year) disproportional analysis of covariance of organ weights revealed that liver weights for pregnant females were significantly heavier ($P < .01$) between the control and test area beachmice, and these differences were consistent over the five years of observation. These studies suggest that long-term, low level exposure to TCDD under field conditions has had minimal effect upon the health and reproduction of the beachmouse.

TEST AREA C-52 A

EGLIN AIR FORCE BASE, FLORIDA

- . A TEST RANGE USED IN THE DEVELOPMENT OF
DEFOLIATION SPRAY EQUIPMENT FOR SOUTHEAST ASIA
- . HERBICIDES SPRAYED ON THE TEST AREA, 1962-1970.

TEST GRIDS AND QUANTITIES OF 2,4,5-T
APPLIED TO TEST AREA C-52A, EGLIN AFB FL

<u>GRID</u>	<u>AREA (HA)</u>	<u>YEARS</u>	<u>2,4,5-T (KG)</u>
I	37	1962 - 1964	39,550
II	37	1964 - 1966	15,890
IV	97	1968 - 1970	<u>17,440</u>
		TOTAL	72,880

**ECOLOGICAL INVESTIGATIONS, TEST AREA C-52A
1973 - 1978**

SOIL RESIDUES: 2,4,5-T, TCDD

TERRESTRIAL ECOSYSTEMS

VEGETATION

ANIMALS

VERTEBRATE

INVERTEBRATE

MICROORGANISMS

AQUATIC ECOSYSTEMS

ANIMALS

VERTEBRATE

INVERTEBRATE

MICROFLORA

ECOLOGICAL SURVEY, 1973 - 1978
TEST AREA C-52A

<u>NUMBER OF SPECIES</u>	<u>ORGANISMS</u>
123	PLANTS
77	BIRDS
71	INSECT FAMILIES
20	FISH
18	REPTILES
18	MAMMALS
12	AMPHIBIANS
2	MOLLUSCS

170 BIOLOGICAL SAMPLES ANALYZED FOR TCDD

CONCENTRATION OF TCDD (PPT) IN TEST GRID SOILS

<u>GRID</u>	<u>NO. SAMPLES*</u>	<u>RANGE</u>	<u>MEDIAN</u>	<u>MEAN</u>
I	22	< 10 - 1,500	110	326
II	6	< 10 - 470	30	117
IV	26	< 10 - 150	19	27

*0 - 15 CM INCREMENT

DISAPPEARANCE OF TCDD FROM SOILS OF GRID I
(PARTS PER TRILLION)

<u>PLOT*</u> <u>NUMBER</u>	<u>AUGUST</u> <u>1974</u>	<u>JANUARY</u> <u>1978</u>
1	1,500	420
2	610	300
3	1,200	580
4	270	100
5	<u>440</u>	<u>400</u>
MEAN	804	360

*FIVE SUBSAMPLES FROM EACH 1-M² PLOT
COMPOSITED (0-10 CM DEPTH)

INVESTIGATIONS OF BIRD SPECIES **Test Area C-52A**

77 Species Observed

DOMINANT SPECIES	TCDD RESIDUE ANALYSIS (PPT)			
	No. Samples*	Organ	Range	Mean
Southern Meadowlark	3	Liver	100 - 1,020	440
	1	Stomach		10
Mourning Dove	2	Liver		50
	1	Stomach		10
Savannah Sparrow	1	Liver		69
	1	Stomach		84

***Composites from at least 6 birds**

INVESTIGATIONS OF INSECTS

Test Area C-52A

71 Families Observed

<u>FAMILY</u>	<u>TCDD Residue Analysis (ppt)</u>
Grasshoppers	ND (3)*
Crickets	26
Composite of Soil/Plant Insects	40

*Detection Limit

INVESTIGATIONS OF MAMMALS, TEST AREA C-52A

SPECIES	TCDD RESIDUE ANALYSIS (PPT)		
	<u>ORGAN</u>	<u>CONCENTRATION</u>	<u>DETECTION LIMIT</u>
DEER	FAT	ND	4
	LIVER	ND	5
	KIDNEY	ND	4
OPOSSUM	FAT	ND	10
	LIVER	ND	10
RABBIT	LIVER	ND	8
	PELT	ND	2
COTTON RAT	LIVER	10 - 210	
BEACHMOUSE	LIVER	300 - 1,500	
	PELT	130 - 140	

STUDIES OF THE BEACHMOUSE, PEROMYSCUS POLIONOTUS
Grid 1, Test Area C-52A, Eglin AFB FL

LOCATION	YEAR				
<u>Maturity, Sex</u>	<u>1973</u>	<u>1974</u>	<u>1975</u>	<u>1978</u>	<u>Total</u>
CONTROL AREA					
Mature					
Male	4	11	3	2	20
Female	3(3)	8(3)	3(1)	2(2)	16(9)
Immature					
Male	1	1	0	0	2
Female	0	2	0	0	2
Fetuses	12	11	3	5	31
				Total	<u>71</u>

() Number of Pregnant Females
 Fetuses/Pregnancy = 3.4

STUDIES OF THE BEACHMOUSE, PEROMYSCUS POLIONOTUS
Grid 1, Test Area C-52A, Eglin AFB FL

LOCATION:	YEAR				
<u>Maturity, Sex</u>	<u>1973</u>	<u>1974</u>	<u>1975</u>	<u>1978</u>	<u>Total</u>
TEST GRID 1					
Mature					
Male	18	14	7	7	46
Female	15(6)	9(6)	6(4)	6(6)	36(22)
Immature					
Male	8	3	7	6	24
Female	1	4	3	3	11
Fetuses	25	9	12	21	67
				Total	<u>184</u>

() Number of Pregnant Females
 Fetuses/Pregnancy = 3.1

MEAN LIVER WEIGHTS (MG) OF PREGNANT BEACHMICE
TEST AREA C-52A

<u>LOCATION</u>	<u>YEAR</u>	<u>LIVER WEIGHT (MG)</u>
Control	1973	929
	1974	765
	1975	934
	1978	919
Grid 1	1973	1, 247
	1974	1, 019
	1975	1, 109
	1978	1, 101

STATISTICALLY SIGNIFICANT!

HISTOLOGICAL PARAMETERS

HEART	PANCREAS
LUNGS	ADRENALS
TRACHEA	LARGE/SMALL INTESTINE
SALIVARY GLANDS	SPLEEN
THYMUS	GENITAL ORGANS
LIVER	BONE
KIDNEYS	BONE MARROW
STOMACH	SKIN
	BRAIN

ALL MICROSCOPIC CHANGES RECORDED. TEST AND CONTROL MICE
COULD NOT BE DISTINGUISHED.

1 for you, that received almost 3,000 grams of TCDD. In
2 the course of developing the spray equipment for Vietnam,
3 we disseminated the actual herbicide on the test site.
4 We were not evaluating the herbicide, we were evaluating
5 the spray equipment. It didn't all come down at one time;
6 it was distributed over time. And that is the important
7 point to remember. Had it been 3,000 grams at one time,
8 I'm certain we would have had people say something about
9 health effects.

10 But because it was stretched out over a period
11 of eight years, and I was one of the participants in those
12 programs, then I think we've seen a different picture.

13 Let me get right into the slides very quickly.
14 I am only going to cover some of the key points. The
15 actual data we have span 10 years and it is voluminous.
16 I can talk about birds; I can talk about fish; I can talk
17 about deer, opossum, you name it; we can talk about it.
18 Microorganisms, soil, but I am going to focus it on just
19 a couple key areas.

20 Eglin is located in the northwest corner of
21 Florida. On test area C-52A, as I mentioned, the herbicide
22 was disseminated by aerial means into an area of approxi-
23 mately one square mile, 162,000 pounds of 2,4,5-T
24 were disseminated in the time period from 1962 to 1970.

25 The uniqueness, however, of the dissemination is

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1 what is important in that we had some sites that received
the 2,4,5-T herbicide
2 /in the '62 to '64 time period --other sites in '64 to
3 '66, and yet a different site in '68 to '70, therefore,
4 separate
they are / sites -- they don't overlap. They are separate
5 entities and because of the complexity of our monitoring
6 system, we have excellent records on how much herbicide
7 was placed upon each site.

8 What we lack, however, is the actual dioxin
9 content of the material. We have some archive samples.
10 We have analyzed those archive samples. The archive
11 samples for orange indicate a mean concentration of 1.91
12 ppm. The archive sample for purple, the early material
13 applied on grid one. sample of
14 purple was 45 ppm. That is a tremendously high concentra-
15 tion of dioxin relative to orange.

16 Even more important there, we find that that
17 site is the site that was first treated. So, from a
18 time period you are going to see some very interesting
19 data.

20 What we have looked at are the following
21 components, and we have a number of publications out,
22 and some currently coming out.

23 Here is the one square mile fully-instrumented
24 test site. In the center of that test site for those
25 who may or may not be able to see it, there is in fact

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1 a square concrete pad where a 300 foot tower is located.
2 To your right is grid one. Up to your left, the bare
3 area is part of grid three.

4 Here is grid one. We're going to focus primarily
5 on grid one, the site that received all that Herbicide
6 Purple.

7 In 1970, at the termination of all test programs,
8 grid one was still bare and I will show you a picture
9 in a moment to show you what it looked like in 1964 at
10 the termination of that program, of the actual dissemination.
11

12 One of the beauties about this one / square mile
13 instrumented grid is that there is water occurring on
14 these areas and, hence, one can also establish data on
15 the movement of dioxin within an aquatic ecosystem, not
16 only terrestrial, you see, on land, but also in water.

17 Again, this is a picture of grid one, the south
18 end in 1970 and the bayhead, this is where water will
19 begin for a small stream. The bayhead starts right off
20 of grid one and then becomes a stream that goes for 2 1/2
21 miles and empties into Choctawhatchee Bay, an area where
22 there are shrimp and oysters. One might say, well,
23 that would be interesting to follow that from start to
24 finish; and, indeed, we have -- a very thorough study.

25 These are the organisms we have looked at. Not

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1 all of them have been analyzed for TCDD. There are certain
2 ones that are obvious for analysis for TCDD. There are
3 others that would not be. But we have analyzed over 250
4 biological / samples for TCDD and you might think that is not
5 much, but I can assure you that with the state-of-the-art,
6 pressed at its very limit, a single part per trillion
7 we are pushing the state-of-the-art and we have pushed
8 three laboratories almost to their full capacity to produce
9 these data over a period of about five years.

10 The next slide, please?

11 This is 1964, a photograph taken in 1964 of grid
12 one.

13 The next slide is a picture of the same site
14 taken from the same point in 1967.

15 Next slide -- oh, I'm sorry, this is much too
16 dark, but it was taken in 1978 and I can tell you that
17 there are trees out there today. We have seen a very
18 extensive ecological recovery, a succession of vegetation
19 come in, establish itself to the point where in a few
20 years if we want to be able to move / freely over this area,
21 we are going to have to spray it with herbicide.

22 at the test site
23 The soil / Eglin/ is a very sandy soil. One
24 rapid
25 might expect to see/penetration of herbicide.

24 Our studies, spanning many years, have shown that indeed
25 the phenoxy herbicides moved down into that soil profile,

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1 but most of the phenoxy herbicides, 2,4-D and 2,4,5-T
2 disappeared very quickly.

3 As a matter of fact, the microbial degradation
4 was so rapid out there in some of the years, for example
5 1969 and 1970, when we were studying it, an application
6 of orange would only persist anywhere from three to eight
7 days. It would be degraded that fast. So, you would have
8 microorganisms tuned to degrading this material.

9 The next slide.

10 These are the dioxin levels, and they represent
11 samples collected/ ^{from} in 1974 to 1978 for the various grids.

12 Grid one, the grid that received the purple
13 and hence the highest concentration/ ^{of TCDD} the
14 mean concentration ^{parts per trillion} was 326 / in that site
15 ^{herbicide} that received the / so many years ago. So, much,
16 ^{in TCDD content} much higher/. That certainly confirms the fact that
17 it was much more contaminated material/ ^{than} ^{which} that was applied
18 to grid three, an area that received a tremendous
19 amount of herbicide, Herbicide Orange. / ^{Note that} very little
20 ^{was} persistence/ indicated simply because there was not much
21 dioxin.

22 The next slide.

23 These are some data from grid one, and it addresses
24 time. What these data show you is that on grid
25 one, one would expect from these data -- and there are

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and there are not enough data points here to make a good conclusion -- but we would say the half life was 3.4 years for TCDD in the soil. But what is wrong with that? What is wrong with it is when you go back and figure out how much TCDD was probably placed on grid one, you find that the mean concentration, the top six inches, would have been 49,000 ppt versus today what is there (326 ppt). So, greater than 99.9 percent of all the dioxin is gone, as best we can figure. So, although we still see persistence, persistence is related in this case to the massive amount of TCDD that was there.

Sure it breaks down or it disappears, but when you have such a tremendous quantity, one has to put this in perspective.

Now, let us go back and talk for just a minute of how this compares to what happened in Vietnam. The Eglin test site received 1,900 times more herbicide than would have intercepted the ground in Vietnam. 1,900 times more. That puts it in perspective for you. And had we then the capability of looking at the very low parts per trillion, we would have never been able to see some of the data that you are going to see today/ We would not have been able to collect it.

1 limit required. But in '73 and '74, when we began to
2 develop the detection limit, we began to find it. It
3 didn't just all of a sudden appear; it was simply a matter
4 of developing the instrumentation to find it, the state-of-
5 the-art.

6 Next slide, please.

7 Okay. The beach mouse, Peromyscus polionotus,
8 it is a small animal only about 13 grams, but that animal
9 predominates on grid one. And because the laboratory
10 studies of mice have been so significant; for example, the
11 mouse is the most sensitive animal for teratogenesis in
12 the case of dioxin. The most sensitive/^{indicator,} cleft palate, is
13 the characteristic to look for. So, we focused on a
14 population of animals that were indeed highly contaminated.

15 The next slide, please.

16 I am going to ignore now the rest of the studies
17 and focus on the beach mouse because those are where our
18 best and most thorough data/^{exist} We have followed almost
19 50 generations of beach mice since 1974 and we're still
20 doing work in this area.

21 Okay, the little beach mouse, a lovely animal to
22 study.

23 Next slide.

24 We have had the opportunity, because of the
25 sandy soil -- this is a beautiful part/^{to study the habitat} Now, most people

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do field work by using traps, not at Eglin. The shovel is the tool, because it is a very sandy soil and we can dig out the nest, the female, the male and the offspring. It is fantastic. We have whole families / We have the capability of looking at individual livers in the female and the male, and I am going to show you some data now that shows you the significance of this.

The next slide.

these data
Look at / For those of you that have never

seen these kind of data, these are really unique data because we have a single female that we have analyzed from a burrow that we have also examined the and nest/ the soil levels of TCDD. We know what her liver level is because that is ^{the} site of the accumulation for most dioxin in the beach mouse. There is no fat in beach mice. They are always on the edge of survival. Always looking for food. They don't have time to put fat on.

And you always find that females ^{are}/almost always pregnant.

(Laughter.)

MAJOR YOUNG: Another survival characteristic of the beach mouse. The pregnancy ^{period} is 28 days, therefore, one can follow many generations very quickly.

The hide, this is the fur / ^{or} the pelage is contaminated, and this route, of perhaps

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1 contamination. We'll talk about it in a moment.

2 beach mouse
3 There are the/pups. These are young mice
4 that still cannot get out of the nest, but we took those
5 pups; and looked at liver level and the
6 of TCDD
7 hide level. She was pregnant with four fetuses. We were
8 able to then aseptically remove those from the female
9 and analyze them for dioxin. What you see is that they
10 are contaminated also, suggesting placental transport for
11 TCDD. Very interesting!

12 We were able to look at the burrow two, which was
13 right next to this and found the same sort of situation.
14 We combined the two males from those two holes. Males
15 always accumulate more TCDD than the female. There is a
16 concentration factor of 8 for the females no matter where
17 you're at on the test site, and there is a concentration
18 factor of 18 for the males. And it is so consistent.
19 In the laboratory it is about 25, you see, for the males.
20 So, our field data and the laboratory data are very
21 consistent.

22 Next slide.

23 Now, in this case we are going to a site that
24 is much more contaminated and because the soil is much
25 more contaminated, one sees higher levels in the female and
26 higher levels in the male. And, again, the female in this
27 case was pregnant and the whole body analysis ^{of the pups} was 150 ppt,

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1 which reflects the increased amount of dioxin in the
2 environment.

3 The next slide.

4 How long does it take a beach mouse to be
5 contaminated? That is a very important question. If you
6 were to go into the site, how long must you be affiliated
7 with that soil before you pick it up?

8 In the case of the beach mouse, the half life
9 of the beach mouse is about 90 days because of very heavy
10 predation, but that is enough time for a beach mouse to
11 become contaminated, as we will show you.

12 We took beach mice from a control site; raised
13 many of them in the laboratory; released some
14 300 in the field in this one particular experiment and
15 then recaptured them at various times.
16 And what we found was about 90 days was required for
17 contamination.

18 The next slide.

19 These are the important data. Over the years
20 from '73 to '78, we have had four intensive years of
21 sampling control and test populations of the beach mouse.
22 An important point is that if you sample too hard on
23 year number one, 1973, you will eliminate your population
24 for future / years, you see, because you wipe out your popula-
25 tion. You must always be careful about not taking too many

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1 beach mice or you will eliminate your population, and
2 that is why the numbers are fairly low.

3 Let's take a look at the next -- by the way,
4 the parentheses refer to the number of pregnant females,
5 the number of fetuses per pregnancy is 3.4 for our controls.

6 Next slide.

7 It is 3.1 for our animals from the test site.
8 In this case we have 184 animals we've looked at. You can
9 see the number of fetuses, 67 versus the number we had for
10 the control. That number is not different. 3.4 is not
11 different from 3.1.

12 The next slide.

13 Now, we have taken all of these animals, fetuses,
14 immatures, matures. We've submitted them in a blind system
15 to the Armed Forces Institute of Pathology. We only told
16 them that they were beach mice.

17 They, then, did a complete work-up on 18 differ-
18 ent systems. We're talking about the brain,
19 the genical systems, liver, and so on.
20 A very, very thorough work-up. They did it first on a
21 blind basis and then we went back and told them which ones
22 came from the test site and which ones came from the
23 control. They, then, reexamined on that basis. Histo-
24 logically we saw no differences between exposed and contro-
25 l population.

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1 Next slide.

2 One of our scientists then pursued the liver
3 though ultra-structural studies. Now, we are
4 looking at the endoplasmic reticulin, smooth
5 and rough because if we do not see it at the histological
6 level, the cell level, perhaps subcellularly we can see
7 a difference. And he found no differences.

8 But we did see a toxicity symptom.

9 The next slide.

10 One potential toxicity symptom/^{we found} was an increased weight
11 of the liver and, specifically, in the female because
12 almost all females were pregnant, the / ^{difference occurred in this} a pregnant beach
13 mouse. If the animal was not pregnant, one found that
14 the female was immature and was not ^{capable}
15 of conception.

16 The males did not show the same increase in
17 liver weight.

18 But look at this characteristic over
19 time, all four years, spanning a five year period,
20 showed the same exact trend. Highly significant.

21 So, what I am saying is: we have seen in a study
22 these of/animals over a 50- generation period,
23 no anomalies in terms of histology or reproduction.
24 We have seen a/^{potential} toxicity symptom which /^{was an} increase in/^{liver} weight.

25 That is it in a nutshell, Doctor, that's very

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1 quick.

2 DR. SHEPARD: Thank you very much.

3 I have just been informed that we don't have
4 to evacuate the room at 1:00 o'clock as I originally
5 though.

6 I would like to make, first of all, a couple of
7 announcements and then open up the floor to questions.

8 When we last met, I think I reported to you
9 that I had recently been privileged to attend a meeting in
10 Rome on the impact of dioxins on the environment. This
11 meeting has been alluded to by Dr. Reggiani, who played
12 a prominent role at that meeting. Dr. Moses was there,
13 chaired one of the sessions.

14 Because of the high level of interest in that
15 meeting and the excellence of the subject material and
16 the way it was presented, a number of us have been inter-
17 ested in the possibility of having a follow-on meeting
18 this year, this calendar year somewhere in the States.
19 This will allow for ^{greater} / U.S. participation. Plans are
20 currently moving forward to have such a meeting here in
21 Washington the last week in October. We are working with
22 a number of organizations and we will keep you informed
23 on the progress of that meeting.

24 Another activity to which I did not allude,
25 and should have, of great interest to the VA is the fact

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1 that a number of states are conducting activities and
2 have organized commissions on Agent Orange. I have been
3 privileged to be in touch with some of these states. I
4 was first asked to testify before the Minnesota State
5 Senate Veterans Affairs Committee. I was subsequently
6 asked to attend a meeting in New York State. The Agent
7 Orange Commission of New York State is well underway
8 in its plans for a mortality study headed up by Dr. Peter
9 Greenwald, the Director of Epidemiology for the State
10 Department of Health in New York.

11 I was more recently privileged to attend the
12 meeting of the New Jersey State Dioxin Commission --
13 excuse me, Agent Orange Commission, and I note, with
14 pleasure, that some members of that Commission are
15 with us today.

16 I certainly encourage the states to undertake
17 appropriate areas of research. The one plea that I make
18 is that they not start epidemiological studies which would
19 conflict with studies that have already been mandated
20 by Congress to the VA, not that I think we're any better
21 able to conduct these studies, but it is possible that
22 we will be studying some of the same population groups
23 and that might pose a problem.

24 There are a number of areas of research
25 which would appropriately be addressed by the states,

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1 as New York is already doing. I would encourage
2 state representatives to look upon those as examples of
3 very fruitful work that can be productive.

4 I would now like to open the meeting to questions
5 from the floor.

6 COMMENTS AND DISCUSSION

7 DR. SHEPARD: I have one question from Todd
8 Ensign of Citizen Soldier, this question is directed to
9 Dr. Reggiani.

10 If there is no evidence of significant difference
11 in long-term health effects between Seveso residence and
12 nonresidence, for what reason did Hoffman-LaRoche recently
13 agree to pay \$109 million as settlement of all claims
14 arising from the 1976 accident?

15 Do you have that --

16 I don't like to put Dr. Reggiani on the spot,
17 so -- if he has that information and wants to share it
18 with us, we would be delighted to have it.

19 DR. REGGIANI: May I have, again, the question.
20 just to be sure that I don't/^{say}anything stupid?

21 DR. SHEPARD: If there is no evidence of
22 significant difference in long-term health effects between
23 Seveso residence and nonresidence, for what reason did
24 Hoffman-LaRoche recently agree to pay \$109 million as
25 settlement of all claims arising from the 1976 accident?

DR. REGGIANI: I do not/understand exactly the question. The fact that no health effects, meaning by that, toxic effects, have occurred does not mean that the population there did not suffer.

I am, perhaps, the one who is responsible for that effect. When the accident occurred and we started analyzing the vegetation--during the first two weeks -- around the factory, or let's say a certain part of the territory, there were that large amount of TCDD. It was possible to make a map to locate geographically exactly the position and the concentration of the contamination of the territory contaminated.

I went to Italy. I requested the Italian authorities to evacuate the population from that part of the territory. Now, that is in / ^{itself} ^{adverse} was an / effect. If I would come over to your house, and I would ask you to just leave the house, leaving behind all your belongings taking along with you your kids, your wife, and then leave your job, your surroundings, your neighbors, friends, and go away to a small room in a hotel and stay there, and then you would ask me why, and I would have difficulty in explaining to you why. Of course, at that moment, I said, but you know, TCDD. you never heard about that, but it is the most toxic man made substance which we know of.

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1 Therefore, we have a lot of toxicity around
2 here and you are in risk, and you have to get away.

3 And so the question is: whether you would pay
4 for that? Of course, we would pay that.

5 The next question would be: how long?
6 I would say, I don't know. Perhaps forever. Perhaps you
7 have lost your house forever. Isn't that something that
8 we have to pay for?

9 Concerning the question of health effects, we are
10 happy that there have not been any. But an accident
11 occurred there; and we were responsible for that. It
12 occurred in our plant and I think that is just what we had
13 to do.

14 DR. SHEPARD: I think probably, if I may interpret
15 the question, what may have been in back of the question.
16 Was there anything that was being compensated for in terms
17 of health --

18 DR. REGGIANI: No.

19 DR. SHEPARD: -- resulting from this explosion?

20 DR. REGGIANI: No, not at all.

21 The question of health effects will come up at
22 the moment when we will have the trials in court and that
23 will be probably next year in the spring or autumn.

24 The judge who is holding the investigation of that case
25 has received claims from 17 people, mainly children with

1 chloracne. And that's all for the time being. No claims
2 with respect to any other effects. No claims in respect
3 of neurologic effects, liver. No claims for birth defects
4 or abortions. No claims for any other parameters which
5 have been examined, There are only 17 cases,
6 three of them are adults, the other are children and
7 they have chloracne.

8 We know the complete history of all of those
9 and they will have to be compensated. Well, in fact, we
10 will make the compensations already before the trials
11 because in that case, too, it is our responsibility.

12 Now, perhaps if you don't mind, Dr. Shepard,
13 about this \$109 million, I mean, a part of that has been
14 paid to the Italian state because they have a lot of
15 expenses. They had to mobilize the Army; they had to do
16 a lot of things and a part of that has been paid to the
17 authorities of the Lombardy region for a lot of work
18 that they have done.

19 A part of that money has been paid directly to
20 the people living in the surrounding area -- in these 11
21 communities because, for instance, all the agriculture
22 activities had been stopped. There are just several
23 square miles there where only now the normal activity,
24 the growing of crops, vegetables in the garden, and so on,
25 is just starting again, but it had been stopped all these

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1 years. All the vegetables, all the crops have been
2 collected and analyzed, and then were set aside, but have
3 not been sold. And then there were a lot of small
4 industries in these 11 communities which have a loss in
5 their profit and we had to compensate for that.

6 But that's just to give you some idea of what
7 these \$109 million represent and why they have been paid.

8 DR. SHEPARD: Thank you very much, Dr. Reggiani.

9 A couple of other questions from Todd Ensign.
10 One addresses the videotape. Is it essentially the
11 same as the one shown last December?

12 It is essentially the same.

13 Number two, many of us were shocked to learn of
14 secret tests performed on prisoners performed by Dr.
15 Albert Kligman under contract by Dow in 1964 to '67.
16 What steps has this Committee taken to obtain details
17 from all such studies, including any which may still be
18 undisclosed?

19 I think Dr. Hobson may be able to answer that.
20 He has looked into the matter to some extent.

21 Larry, could you enlighten us on that subject?

22 DR. HOBSON: The results of those tests reached
23 the public knowledge because of the testimony at the EPA
24 hearings and were reported by one of the men from Dow,
25 who did not himself conduct the study. I understand that

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1 a more complete description of the tests and the results
2 is available and we hope to have it fairly soon.

3 The question of obtaining results of other
4 previously unknown studies is a little difficult for us
5 to tackle. We have no police rights to insist
6 that people report to us data they have not previously
7 seen fit to report. And you can be sure that whenever we
8 hear of any such thing, we will go after it.

9 I might say that these were not secret tests
10 conducted as best as I can determine, and from what I
11 know of the situation at that time. They were tests
12 conducted on prisoners, to be sure, and they were done for
13 a private company. They were not put into the public litera-
14 ture, but it was known to the prison authorities that
15 they were being conducted. I would hardly call them
16 secret tests. I think that is a little overstatement of
17 the state of affairs.

18 DR. SHEPARD: Thank you, Larry.

19 DR. KOLBYE: They were skin painting studies,
20 too, weren't they?

21 DR. HOBSON: Yes.

22 DR. KOLBYE: Right.

23 DR. SHEPARD: If anybody else from the
24 Committee has knowledge of this, please feel free to speak
25 up.

1 DR. HOBSON: Incidentally, there was some
2 distortion of this in some of the newspaper reports. It
3 sounded as though he had injected or fed this material
4 to the prisoners. He did not. He applied ^{it} to a small
5 area of skin on the body, not internally.

6 DR. SHEPARD: Are there any other questions
7 from the floor?

8 (No response.)

9 DR. SHEPARD: I apologize to Dr. Moses for having
10 cut her off so quickly. We can now open up the questions
11 to her.

12 Yes?

13 DR. KOLBYE: Dr. Moses, was there any problem
14 when viewing the data concerning prior exposure of present
15 chloracne with confounding exposures to other chemicals
16 that induce chloracne?

17 DR. MOSES: No. We didn't really find that
18 to be a problem.

19 It was something that we were quite concerned
20 about. It turned out not to be a problem because

21 most of the workers at this particular plant

22 started working there after high school or when they
23 came back from the service and generally stayed there.

24 We did take lifetime occupational histories on all of the
25 people. Except for that one case that I showed you

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1 who possibly may have had some PCB exposure,
2 we were able to clearly establish that it was related
3 to their work at Monsanto.

4 DR. KOLBYE: Just to follow that through. There
5 were no other chemicals other than the 2,4,5-T made during
6 that plant or in that time frame?

7 DR. MOSES: Now, there was --

8 DR. SHEPARD: Let me just say, the microphones
9 without the lights are not for purposes of PA, they feed
10 into the reporter's apparatus, so the PA ones are hooked
11 up with the lights.

12 DR. SUSKIND: Dr. Kolbye, I think you were here
13 at the last Committee meeting. I wasn't here, but
14 Dr. Gaffey presented a recently completed study, which
15 was publicized, about 884 workers in that plant working
16 from 1955 on, who were on the record as having been
17 employed from 1955 on. One of the confounding
18 problems -- there are many confounding problems because
19 this is a plant which manufactures, as Dr. Moses so well
20 pointed out, rubber additives since 1929, and there were
21 many chemical agents, but in the '50s, the thing that
22 arose, an outbreak of bladder cancer due to paraaminobi-
23 phenol -- some of the 2,4,5-T exposed people were also
24 exposed to paraaminobiphenol. Some of the people who
25 were even actively employed at the time Dr. Moses did her

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1 study were on monitoring -- biological monitoring for
2 bladder cancer and had cystoscopies yearly, about every
3 six months.

4 But there were other chemicals as well. Some
5 with of them/known toxicity, so that there are confounding --

6 DR. MOSES: Yes, but if I could --

7 DR. SUSKIND: -- but not with respect to
8 chloracne.

9 DR. MOSES: -- with respect to chloracne, which
10 I think is what the question was.

11 I would like to make it very clear that possibly
12 the others, and if someone wants to discuss the bladder
13 cancer, that's an important thing to discuss, but in terms
14 of chloracne I think it is very clear from the company
15 and from the worker and from what we know has been made
16 at that plant, that the chloracne in this group was
17 clearly related to trichlorophenol manufacture. I don't
18 think there is any -- I don't think Dr. Suskind would
19 question that, if that's the question.

20 DR. SUSKIND: Thank you.

21 DR. SHEPARD: Are there any other questions for
22 Dr. Moses?

23 Dr. Gross?

24 DR. GROSS: I have a question for Major Young.
25 In view of the distinction that Dr. Moses seems to draw

1 between an effect and an injury, would you consider a
 2 statistically significant increase in liver weight of
 3 a beach mouse, what effect and injury, or both?

4 MAJOR YOUNG: Dr. Reggiani said a compensation.

5 (Laughter.)

6 MAJOR YOUNG: Well, certainly it / ^{may be} a sign of
 7 the liver toxicity. As to whether / is injured we see no
 8 pathological anomalies in the liver, but it / ^{cannot be ruled out as} a sign of
 9 toxicity.

10 Interestingly enough, ^{Eglin} all the
 11 digging of those/soils was done
 12 those were done by one research team for all those
 13 years. You talk about digging fox holes, it was absolutely
 14 something to see a team go after a beach mouse. They
 15 live 18 inches down in the soil and you dig up about
 16 12 feet of tunnel to get to that beach mouse.

17 So, a few years ago, in 1979, two of the members
 18 of our beach mice digging team volunteered for a fat
 19 biopsy and participated
 20 in The VA biopsy study. / ^{Their fat levels} were found to be negative for
 21 TCDD. I thought it was very interesting, but it is only
 22 two people; but it was two people though who spent a lot
 23 of time digging in the soil. The one individual had
 24 6,000 hours of documented work on the test range; the
 25 other about 1,500 hours of documented work, for what it is

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1 worth.

2 DR. SHEPARD: Any other questions?

3 Dr. Murphy?

4 DR. MURPHY: Dr. Young's comment about fat
5 biopsies reminded me of -- do we have any more informa-
6 tion regarding biopsy results -- results of biopsy
7 analysis in the --

8 DR. SHEPARD: Larry, do you want to address
9 that? Larry has been working very closely with this issue.

10 DR. HOBSON: This touches a very sore nerve
11 with me.

12 The study that we undertook was really done as
13 a feasibility study to see whether we could get useful
14 and feasible results by biopsy using a specific technique,
15 namely that of Dr. Michael Gross. Dr. Michael Gross has
16 not yet completed a manuscript to publish his methodology.
17 Since ours is a feasibility study specifically related to
18 that methodology, we can't very well publish prior to the
19 appearance of his technique.

20 He tells me that he is now in the last revision
21 of that paper and as soon as he gets the paper to me,
22 we will be prepared to publish our results simultaneously.

23 I do want to correct something that Major Young
24 said, and I suspect this is because he hasn't had the
25 full disclosure of this, so I will take the full responsi-

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1 bility for that. Of the three Air Force personnel, one of
2 whom was Major Young; the other two he mentioned. There
3 was one individual who had a negative result. The other
4 two had a very low content, much as we found variations
5 in content to people who had never been, as far as we know,
6 in any contact with Agent Orange or presumably TCDD,
7 we can say that.

8 DR. SHEPARD: Yes, Dr. Suskind?

9 DR. SUSKIND: I wonder if I could follow-up on
10 a comment made by Dr. Hobson on apparently never exposed
11 to TCDD. I think all of you know that 2,4,5-T was used
12 in millions of gardens throughout the country from 1968
13 until 1970, and I am sure that those of you who are
14 gardeners still have cans of herbicides in your garden
15 room which may have TCDD in it, as well as 2,4,5-T. So
16 that there is -- it would be very difficult to find
17 people who grew up in the period of 1948 to 1969 and who
18 were adults during that period who were not exposed --
19 through 1948 to 1970 who were not exposed to TCDD.

20 So that getting controls for anything that you
21 do with 2,4,5-T is a very difficult thing. You'll have
22 to wait a long time to get nonexposed people.

23 DR. SHEPARD: I think what Dr. Hobson may have
24 meant was that people exposed or not exposed to Agent
25 Orange rather than TCDD per se.

1 DR. SUSKIND: Well, I just want to point out
2 that the formulae that was used in every man's garden,
3 every person's garden, contained largely 50 percent 2,4,5-T
4 and 50 percent ^{2,4-D} / It was very similar to Agent Orange.

5 DR. SHEPARD: But probably in a more diluted
6 form, don't you think?

7 DR. SUSKIND: Yes, indeed it was.

8 DR. SHEPARD: Yes, sir.

9 Mr. Collins?

10 MR. COLLINS: If I may, Dr. Suskind, my name is
11 Harold Collins. I'd like to point out the terminology
12 here. I've worked with 2,4-D and 2,4,5-T since 1959.
13 2,4,5-T is not normally a garden chemical. It has been
14 used on turf around the home and was used so for a long
15 time providing for exposure to a large segment of the human
16 population, but it is not a chemical normally associated
17 with garden-type food production.

18 DR. SUSKIND: I am talking actually about
19 the esters of 2,4,5-T, not the free acid, and, not now,
20 but if you would like the trade names
21 of garden weed killers with contain esters of 2,4,5-T, I
22 would be happy to supply them to you.

23 MR. COLLINS: That's fine.

24 DR. SHEPARD: Any other questions or comments
25 from the Committee, floor?

1 Yes, sir?

2 DR. MURPHY: Dr. Young, what is the sensitivity
3 of the beach mouse to the acute toxicity of TCDD?

4 MAJOR YOUNG: What's the LD-50 of the beach
5 mouse?

6 DR. MURPHY: Right.

7 MAJOR YOUNG: It is unfortunate, I can't give
8 you that answer.

9 DR. MOSES: Why not?

10 MAJOR YOUNG: Dr. Moses is asking why not.
11 We were not in position to do those studies in-house.
12 We have had a number of organizations actually
13 offer to do that. We have not pursued it, but we do have
14 the beach mice to do that. It takes quite a few. And that
15 is one of main reasons that we haven't wanted to deplete
16 our control site. We haven't found very many sites where
17 you can get beach mice that are not contaminated with other
18 chemicals.

19 You see, the Florida area has a dog fly problem
20 and years ago DDT was sprayed massively to control the dog
21 fly. The Eglin test site -- test area C-52A was a closed
22 range. It never received any other material to any
23 degree. So, as you do a background analysis, as Dr.
24 Gross of the University of Nebraska did for us, we sub-
25 mitted those animals to him, our control populations and

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1 our test populations and he came back and said, those are
2 the cleanest animals I have ever seen for chlorinated
3 hydrocarbons with the exception of dioxin in the test
4 animals.

5 We got animals from the beach and submitted those
6 and they were loaded with DDT. They were loaded with PCB
7 and so one of our concerns has been, we do an LD-50, let
8 us take animals that are not contaminated with these
9 others and challenge them. But we haven't been able to
10 build up a significant population.

11 We did, by the way, in of our laboratory studies
12 have a quite large number of animals. Then we found out
13 that the bedding they were using was contaminated with
14 PCB and those animals all had to be destroyed and not
15 brought into our test group.

16 It is a very frustrating issue in that regard.
17 Likewise, I would like to see the liver studies done be-
18 cause I think that increase in weight may reflect enzymatic
19 changes.

20 DR. MOSES: You mean the semi-induction?
21 Induction, I mean?

22 DR. MURPHY: Your electronmicroscopy didn't show
23 that, did it?

24 MAJOR YOUNG: They didn't show any abnormalities.
25 But that still doesn't say that there's a very low level

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1 of biochemical change there might in fact be biochemical
2 changes, and not reflected by the smooth endoplasmic
3 reticulin.

4 DR. SHEPARD: Any other questions or comments?

5 (No response.)

6 DR. SHEPARD: In keeping with our regularly
7 quarterly schedule, I would anticipate that our next
8 quarterly meeting of this Committee would be the first
9 week of May, but we will get that word out to all of you
10 well in advance of that time.

11 If any of the members of the Committee
12 have suggestions for appropriate agenda topics, agenda
13 items for our next meeting, please get in touch with me;
14 we need your input, or anybody else for that matter.

15 Thank you very much.

16 (Whereupon, at 12:40 p.m., the Advisory Committee
17 on Health-Related Effects of Herbicides, was adjourned.)

18
19 REPORTER'S CERTIFICATE

20 I hereby certify that the foregoing is a true
21 and accurate transcription of the proceedings of the
22 meeting of the Advisory Committee on Health-Related Effects
23 of Herbicides, held at the Veterans Administration Central
24 Office, Washington, D.C., on Wednesday, February 4, 1981.

25

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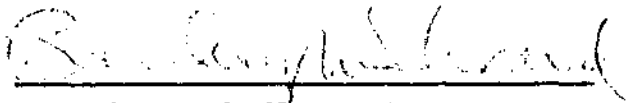
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1 I hereby certify that the proceedings and evidence
2 herein are contained fully and accurately, as corrected.

3 

4 BARCLAY M. SHEPARD, M.D.
5 Chairman
6 VA Advisory Committee on
7 Health-Related Effects of Herbicides
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Advisory Committee on Health-Related Effects of Herbicides Transcript of Proceedings

**(Eighth Meeting
May 5, 1981)**

WJM/cb

VETERANS ADMINISTRATION

ADVISORY COMMITTEE ON HEALTH-RELATED
EFFECTS OF HERBICIDES

Veterans Administration
Central Office
Room 119
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Tuesday,
May 5, 1981

The Committee met, pursuant to notice, at 8:30
a.m., BARCLAY M. SHEPARD, M.D., Chairman, presiding.

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P R O C E E D I N G S

[8:42 a.m.]

CALL TO ORDER AND OPENING REMARKS

Dr. SHEPARD: Good morning, Ladies and Gentlemen. I believe we are ready to begin our program.

We would like to welcome you to our quarterly meeting of the VA Advisory Committee on the Health-Related Effects of Herbicides.

This morning, we would especially like to welcome Mr. Fred Mullen who is a newcomer to the committee. Those of you who were with us at our last meeting remember Mr. Mullen as having addressed the issue of arsenicals and cacodylic acid, and the concerns that some individuals have expressed in this regard.

Mr. Mullen is here as a representative of one of the well-known national service organizations, the Veterans of Foreign Wars.

We also regretfully announce the resignation of Mr. Ron DeYoung who has served as a very active member of this group. Because of the press of other duties, he felt obliged to resign from the committee. His replacement has not yet been named, but the matter is under consideration.

It has been just over a year since I was tasked to head up the Agent Orange activities of the Veterans

2.
1 Administration and, as part of that, to chair this commit-
2 tee. I must say that it has been a source of considerable
3 gratification to me to observe the hard work and efforts of
4 the members of the committee.

5 I wish to express my personal appreciation for
6 your continued interest and very valuable contributions.
7 I think that this committee has established an enviable
8 record in its pursuit of many aspects to a difficult
9 problem.

10 I know that I speak for Dr. Custis, the Chief
11 Medical Director, and certainly for Mr. Cleland, the past
12 Administrator. I am sure that when he is confirmed, the
13 new Administrator will be most interested in getting an
14 update of the activities of this committee.

15 I had hoped that would have already taken place.

16 I was hoping to make one of the highlights of this
17 meeting an introduction of our new Administrator.
18 He was nominated last week and has not yet been confirmed. We hope
19 it won't be long now.

20 We have a full agenda this morning. We have a
21 few people who are here as alternates: I would like to
22 recognize Dr. Thomas Fitzgerald, who is no stranger to
23 many of you, I'm sure. He served many distinguished years
24 in the Veterans Administration and now works at the
25 American Legion.

1 Good morning, Dr. FitzGerald.

2 DR. FITZGERALD: Good morning.

3 Dr. SHEPARD: Dr. Henry Spencer is here,
4 representing Dr. Adrian Gross, for the Environmental
5 Protection Agency.

6 Dr. Albert Kolbye, who is a relatively new member
7 of the committee from the Food and Drug Administration
8 could not be with us this morning; but Dr. Samuel Shisko
9 will represent him in our deliberations.

10 First of all, I would like to be sure that all of
11 you have signed in, so that we can keep a record of atten-
12 dance. If you have not done so, will you please do so at
13 the break.

14 I hope there is still some coffee available.
15 Feel free to help yourselves.

16 I would like, first of all, to call upon Dr.
17 Matthew Kinnard who works in our Medical Research
18 Service and has been tracking the Epidemiological
19 Study efforts over the past year and a half.

20 He has some very exciting news to share with us,
21 and without stealing his thunder I will turn it over to
22 Matt.

23 EPIDEMIOLOGICAL STUDY

24 DR. KINNARD: Thank you Dr. Shepard.

25 First, I would like to express, on behalf of Dr.

4.

1 Larry Hobson, his regrets that he could not be here on
2 what I think is one of the more important advisory committee
3 meetings since they began because of what has transpired since the
4 previous one.

4 Dr. Hobson is the senior VA representative on
5 the Interagency Research Radiation Committee, which is
6 convening right now at the National Institutes of Health.

7 I am pleased to announce that at long last an
8 award has been made--

9 --to the University of California at Los
10 Angeles School of Public Health for the design study for
11 the epidemiology investigation of Agent Orange. The award was
12 signed Friday, May 1.

si

12 The amount of this award is approximately
13 \$114,300. The principal investigator of this design
14 study is Dr. Gary Spivey, who will be ably assisted by
15 Dr. Roger Detels, and Dr. Jess Kraus, and a number of other
16 lesser-involved individuals on the design study.

17 I think it would be in order to give a brief resume of
18 the background and expertise of the three prin-
19 cipals on this contract.

20 Dr. Spivey is an Associate Professor in the
21 School of Public Health at UCLA. He obtained his Bachelors
22 Degree from the University of California at Davis, his
23 MD at the University of California at San Francisco, and his
24 MPh at Johns Hopkins University in Baltimore.

25 Dr. Spivey holds membership in a number of

1 prestigious professional associations and has been the
2 recipient of numerous awards and honors. His publication
3 list is very impressive and ranges over a number of areas;
4 however it is concentrated in the area of environmental
5 contamination.

6 Dr. Spivey's support mainly has been in the form
7 of grants and contracts from EPA, from NIOSH, from NIH--
8 mainly from the National Cancer Institute--and also he has
9 been awarded from the State of California.

10 Dr. Spivey is the principal investigator of the
11 design study.

12 Dr. Roger Detels, who initially was listed as
13 co-principal investigator on the project, however, since the time
14 of the initial submission of the proposal has been elevated to the status
15 of Dean of the School of Public Health.

16 Dr. Detels obtained his Bachelors Degree from
17 Harvard University, his MD from NYU, and a Master of
18 Science Degree in Epidemiology from the University of
19 Washington at Seattle.

20 Dr. Detels, not unlike Dr. Spivey, has an
21 impressive list of publications and memberships in numerous
22 honorary societies.

23 His support has mainly been from the National
24 Institutes of Health, specifically from the National
25 Institute of Neurological Communicative Disorders and

1 Stroke, the National Heart, Lung and Blood Institute, the
2 National Institute of Environmental Health Sciences, the
3 National Cancer Institute, and the National Institute of
4 Child Health and Human Development.

5 Needless to say, his publication record is
6 monumental.

7 Finally, Dr. JessKraus holds an Associate
8 Professorship in Epidemiology at UCLA School of Public
9 Health.

10 He obtained his Bachelors Degree from Sacramento
11 State in California; he also holds a MastersDegree from
12 the same institution; he has a Master of Public Health
13 from Berkeley, and a PhD in Epidemiology from the Univer-
14 sity of Minnesota.

15 He has had numerous assignments both in the Mid-
16 western U.S. and in the State of California. His professional
17 affiliations as well as his publication record are
18 impeccable.

19 He lists a total of 44 publications of which
20 he is at least senior or second author on, and a number
21 of others are in press.

22 Now, in terms of the Epidemiology Design Study,
23 the agreement calls for a preliminary design to be sub-
24 mitted in approximately 60 days from the time that the
25 award was received.

1 It is my understanding that the award was signed
2 and mailed on last Friday, so it is assumed that it will
3 be in the hands of the investigators later this week.

4 Once designed, the study will be sent
5 to Central Office where it will be distributed for review by representatives
6 from
/four prestigious groups namely: the V.A. Advisory Committee on Health
7 Related Effects of Herbicides.....

8 the Office of Technology Assessment,
9 the National Research Council of the National Academy of
10 Sciences, and the Interagency Work Group on Phenoxy Herbi-
11 cides.

12 This is not anticipated to be a highly-polished
13 copy because of the short turn-around time and because it will receive
14 extensive
/input from these various groups.

15 I might mention, at this time, that the veterans
16 will have access to the UCLA group by means of the representa-
17 tives from the veterans organizations on the Advisory Committee.

18 At this time I will pause to allow the committee an opportunity to
19 ask some questions. Dr. Shepard, I am sure, would be very
20 happy to assist me in answering any questions that any of you
21 might have regarding the epidemiology contract.

22 QUESTION & ANSWER SESSION

23 Dr. SHEPARD: Any questions from members of
24 the committee? Yes, Dr. Suskind?

25 DR. SUSKIND: The total time for the preparation

1 of this program is 60 days?

2 DR. KINNARD: Well, as I said, Dr. Suskind--and
3 Dr. Shepard might wish to comment further that--this design is not
4 intended to be final. For lack of a better term, this is a rather
5 preliminary-type design study that will be circulated for review
6 among the four groups that I previously mentioned for input.

7
8 DR. SUSKIND: As a cost-conscious investigator
9 I am just wondering about the total amount of man-hours
10 that are going to be spent on this effort in relation to
11 the \$114,00. Can you answer that?

12 DR. KINNARD: I can answer it somewhat indirectly,
13 and Dr. Shepard may have a further comment.

14 In addition to Drs. Spivey, Detels and Kraus,
15 there are named in the protocol six or seven other indi-
16 viduals who will be taking part in the designing of the
17 study.

18 DR. SUSKIND: And these people are going to
19 spend full time in the preliminary design of an epidemiolo-
20 gical program?

21 DR. KINNARD: Their efforts are not all full
22 time, I am sure. I can't give you details as to what
23 percent of time each one will be spending.

24 DR. SUSKIND: Would it be possible for this
25 committee or any of us who would wish to see the

1 application of the UCLA School of Public Health?

2 Dr. SHEPARD: Yes.

3 DR. SUSKIND: I would like very much to see that.

4 Dr. SHEPARD: Maybe I can just clarify or
5 amplify a couple of points.

6 I have not recently reviewed, in detail, the
7 of participation of each individual
8 member of the team.

9 Dr. Spivey, as I understand, will be in charge
10 of the project and will be essentially full-time on the
11 project.

12 Dr. Detels, who is Dean of the School of Public
13 Health of UCLA, obviously cannot spend full-time on the
14 project.

15 And I think that the others on the team will
16 also be somewhat part-time participants.

17 The 60 days is allocated for a preliminary design
18 which will then be subjected to a series of peer reviews,
19 as Dr. Kinnard has indicated.

20 The contractor will still be responsible for
21 following, monitoring and incorporating the comments of
22 those various peer review groups, so that his duties will
23 not be discharged at the end of 60 days.

24 After the peer review group he will be given an
25 additional 30 days to incorporate and come up with an

1 essentially finished product.

2 So I expect that, since we could not accurately
3 predict the length of time that the peer review effort
4 would take, it's kind of open-ended in terms of exactly
5 when the final product will be delivered. We would
6 anticipate having these peer reviews run
7 concurrently, not sequentially, so that would shorten the
8 time for the reviews.

9 I would hope that we would have something close
10 to a finished product in a period of some six to nine
11 months from now.

12 Are there other questions?

13 DR. SUSKIND: The total amount of effort on the
14 part of the contractor would be about 90 days though. Is
15 that right?

16 Dr. SHEPARD: Well, I would say for intense
17 effort, yes.

18 There is one additional effort that is mentioned
19 in the contract, and that is: during the conduct of the
20 study, the actual conduct of the study, the designing
21 contractor will be responsible for monitoring that process.

22 So there will be an ongoing ^{requirement} ~~requirement~~ for the
23 contractor to stay abreast, current, and be available for
24 a kind of monitoring of the conduct of the study.

25 DR. SUSKIND: Who are the physicians in the

1 development of this study?

2 DR. KINNARD: I don't have all of the CVs, but
3 Dr. Spivey holds an MD Degree, and he is the principal
4 investigator.

5 Also Dr. Detels, who was listed as co-principal
6 investigator on the original proposal, has an M.D. degree, as well as
7 some of the other individuals; but I don't have a complete listing
8 of their degrees.

9 Let me say one other thing. In addition to what
10 Dr. Shepard has said, I don't think it would be advan-
11 tageous to put an inflexible time limit on the follow-up design
12 study once the four groups have commented.

13 I think Dr. Shepard would agree with me , that
14 the VA is interested in the best possible design. So in order
15 to incorporate appropriately all of the ^{relevant} suggestions, I
16 think the VA would be remiss for not giving the designers
17 an adequate amount of time to do this.

18 DR. KEARNEY: Dr. Kinnard, do you have a press
19 release or any information on this?

20 Dr. SHEPARD: Surely.

21 DR. KEARNEY: Could we get hold of this? Because
22 there has been a lot of interest in this, and if we could
23 get a release on it it would be helpful. A lot of the
24 journals that we work with have been quite interested in
25 this.

1 DR. KINNARD: No problem.

2 Dr. SHEPARD: Surely.

3 Our information service has prepared a press
4 release. I'm not sure it has appeared in print--I don't
5 know, Dr. Kearney. Mr. Strat Appleman will get us a copy
6 of that.

7 DR. LINGEMAN: I would like to ask if this is
8 only for the study design? And then another contract will
9 be awarded later to actually conduct the study? Is that
10 right?

11 Dr. SHEPARD: That question is still open.
12 The determination as to who will actually conduct the
13 study has not been made.

14 There have been a number of suggestions made as
15 to how that should be accomplished, but I think it is
16 accurate to say that we do not have a decision.

17 When asked that question my standard answer is
18 that we will look to the contractor as well as to members
19 of the peer review groups to provide us with some guidance
20 as to how the study should actually be conducted.

21 Until we see the design I think it is a little
22 premature to decide who would actually conduct the study.

23 DR. FITZGERALD: Again, Barclay, in that regard,
24 an admonition: As we have said before, we do not imply
25 that the VA would not do a good job; it could do the best

1 possible job and still be suspect to the general public.
2 So, if at all possible, we would advocate that somebody
3 other than the VA do this job, at least have an intimate
4 part of it; otherwise your end product will not be credible
5 in the eyes of a good many people.

6 I do not mean to say that, as I've said before,
7 as an indictment of the VA; but I think it is a reality
8 of life.

9 Dr. SHEPARD: I agree. My guess is that no
10 one group will be solely in charge of responsibility of the
11 conduct of the whole study.

12 I suspect, as has been experienced by the Air
13 Force, that even if the VA remains in control of the
14 conduct of the study--and that question hasn't been
15 answered yet--that parts of it would be contracted out.
16 It may be that the whole thing will be turned over to an
17 outside agency.

18 DR. FITZGERALD: As part of the concern that was
19 expressed by Dr. Suskind concerning this contract, is it
20 not true that you have to have an acceptable product from
21 the contractor before you are accepting it, regardless of
22 the 60 or 90 days?

23 Dr. SHEPARD: That is my understanding.

24 Are there any other questions of Dr. Kinnard?

25 [No response]

1 Dr. SHEPARD: Thank you very much.

2 We are fortunate to have with us this morning
3 Dr. James Striegel, who will give us an update on the other
4 effort mandated by Public Law 96151, namely the analysis
5 of the world literature on phenoxy herbicides.

6 Jim?

7 LITERATURE ANALYSIS REPORT

8 DR. STRIEGEL: Good morning. It's a pleasure
9 to be back here again.

10 As you will recall, ^{JRB Associates} has been tasked to
11 identify, acquire, annotate, conduct a critical review and
12 report on the worldwide literature on all of the herbicides
13 used in Vietnam.

14 We are currently about halfway through this nine
15 month effort; we are on schedule; we have identified about
16 1400 articles that meet our relevancy criteria, which
17 primarily have to do with exposures similar to the Vietnam-
18 type exposures in otherwise healthy adult human males.

19 We anticipate that 1400 or 1500 is probably about
20 as many as we are going to find.

21 We have recently gone through a hand check of our
22 bibliography and have identified about 250 of those
23 articles which are now being deleted upon review of the
24 hard copy itself as not precisely relevant to our criteria.
25 And there were some duplicates and other material in it; so

1 that has been cleaned out.

2 We have about 900 articles inhouse; we have
3 about 250 currently on order, and over 300 have already
4 been annotated.

5 The critical review of the material will begin
6 very shortly. As we get various stacks of paper on mutagen-
7 icity or teratogenicity together, the critical review of
8 the scientific merit will begin.

9 For the record the herbicides of interest that
10 we are working on include Agent Orange and Orange 2, both
11 of which were 2,4-D and 2,4,5-T; Herbicide Purple, which
12 was 2,4-D and 2,4,5-T; Herbicide Pink, which was only
13 2,4,5-T; Herbicide Green, 2,4,5-T; Herbicide White, which
14 was a combination of picloram and 2,4-D; Herbicide Blue,
15 which is cacodylic acid, an arsenical; dinoxol, which was
16 a combination of 2,4-D and 2,4,5-T, which was used in
17 small quantities in test cases in South Vietnam; trinoxol,
18 which was 2,4,5-T, also used in small quantities; and then
19 a variety of other non-arsenical, non-phenoxy herbicides
20 that were used in small quantities in test cases: diquat,
21 bromacil, tandex, monuron, diuron and dalaphon.

22 Now, we are not far enough along in this study
23 for us to be making any kinds of statements about defini-
24 tive findings or the quality of the science, as you can
25 tell by the numbers that I presented a few moments ago.

1 However, if Dr. Shepard and the committee will
2 permit me the leeway of denying tomorrow everything I am
3 about to say today, when I read, when we get further into
4 the science, I would like to hazard a few points that we
5 are kind of making our way toward in our studies.

6 First of all, to begin with the water and work
7 our way to the wine, bromacil, tandex, monuron, diuron
8 and dalaphon have a low order of toxicity. In the words
9 of one of the pharmaco-toxicologists that workson this pro-
10 ject, "They are phenomenally non-toxic."

11 The diquat, another one of the non-phenoxy,
12 non-arsenical herbicides used, is very much less toxic
13 than its structural analog paraquat which hit the news-
14 papers a couple of years ago when the Mexican government
15 chose to spray it on the marijuana in Operation Cobra.

16 The Herbicide Blue, the arsenical containing
17 cacodylic acid; there is a large amount of literature
18 on arsenic and the other arsenicals--not a great deal on
19 cacodylic acid per se. We have not yet gotten into consi-
20 dering the health effects of that substance.

21 Picloram, which was in Herbicide White with
22 2,4-D, we have not gotten into studying yet.

23 Now, the phenoxy herbicides and 2,3,7,8-TCDD,
24 which are orange, purple, pink, green; and dinoxol and
25 trinoxol, which were used in small quantities.

1 As I'm sure all of the members of the committee
2 are aware, the earlier studies used dioxin-contaminated
3 2,4,5-T without specifying the level of contamination,
4 which tends to abrogate their help in the kind of study
5 we are doing.

6 There are very few animal studies on reproductive
7 hazards from exposure to the male only. There are
8 naturally, as you would expect, no controlled human
9 studies with defined exposure to the phenoxy herbicides
10 and/or TCDD exclusively.

11 There are very few animal studies on oncogenesis
12 and chronic exposure. The oncogenicity studies in humans
13 involve exposures to various and often unidentified
14 herbicides.

15 There are many studies of the mechanisms of
16 immunosuppression, enzyme induction, tissue distribution
17 and pharmacokinetics.

18 As for the industrial accidents and exposures,
19 there are common symptoms reported, but there are also
20 symptoms unique to each incident. In all cases there were
21 other chemicals involved, and there have been reports in
22 some of the cases of behavioral symptoms associated with
23 the accident, and we are thus far unable to resolve whether
24 some of those behavioral symptoms are attributable to
25 TCDD, as some of the authors have suggested, or simply

1 to the experience of going through an accident situation.

2 There are, of course, major species differences
3 in TCDD toxicity, including both hepatic and teratogenic
4 effects; but in all species there is delayed toxicity,
5 extremely low LD-50s, thymic toxicity, and weight loss.

6 The dermatological effects seem to be limited
7 at this point in our study to rabbits, monkeys and humans.

8 In general 2,4-D and 2,4,5-T both are moderately
9 toxic in all species, it appears. Both appear to be
10 teratogenic in the absence of TCDD in certain species
11 under certain conditions--that based on female exposure
12 studies.

13 Both appear to be mutagenic in forward mutation
14 tests, not in backward mutation tests; and both appear to
15 be negative in dominant lethal tests.

16 It would appear at this time that both are
17 unlikely to be toxic to humans or animals at agricultural-
18 use levels; that the potential toxic levels would be
19 reached only in an accident situation.

20 2,4-D and not 2,4,5-T causes myatonia at high
21 levels of exposure.

22 The mechanisms of TCDD toxicity are unknown. We
23 know that it is a very powerful enzyme inducer, and there
24 have been some suggestions that that would be one way of
25 studying that problem; and work is being done in that area.

1 From the literature that we have seen thus far,
2 which I remind you is partial--none of these statements
3 that I have made should be considered conclusive at all--
4 it would appear to be not possible to predict body burdens
5 from military exposures in Vietnam.

6 2,4-D and 2,4,5-T do not persist for very long,
7 perhaps less than six months; they do not bioaccumulate
8 in the soil or in terrestrial or aquatic species; the
9 published literature indicates that they are rapidly
10 absorbed, rapidly distributed, not biotransformed, and
11 rapidly excreted.

12 There is very little useful or no published
13 information on the frequency of chloracne or other
14 relevant symptoms in Vietnam veterans.

15 Because of TCDD's inordinately high level of
16 toxicity extremely low levels of exposure become relevant,
17 and that becomes very difficult to measure, of course, in
18 retrospective, historical perspective; which tends to
19 preclude this possibility of obtaining relevant body
20 burden information from the published literature we have
21 seen thus far. There is yet much for us to see, as I have
22 indicated.

23 I would like to thank the members of the commit-
24 tee who provided me with leads, advice, direction, and
25 resources to go to, at the last meeting.

1 I think we followed up on just about all of them
2 in the last three months. They have been very helpful.
3 We, again, look forward to any advice that you can pro-
4 vide to us, and we actively solicit this.

5 I would also like to offer my congratulations to
6 Dr. Spivey at UCLA. I know Gary Spivey and Jess Kraus
7 both; I have worked with them. They are extremely talented
8 epidemiologists, and I give them my very best wishes on
9 what will undoubtedly be a very difficult assignment.

10 Dr. SHEPARD: Thank you, Jim.

11 Jim's graciousness is highlighted by the fact that
12 JRB also submitted a proposal for the design of a study,
13 and I think it is a tribute to that organization that as
14 soon as they were informed of the successful bidder that
15 Jim personally communicated his congratulations to UCLA
16 and offered the services of their literature research to
17 that effort.

18 So I think you are to be congratulated, also.
19 They are good friends.

20 Are there any questions from the members of the
21 committee?

22 QUESTION & ANSWER SESSION

23 DR. MOSES: I was curious -- we are talking
24 about herbicides, and I realize we are in herbicide-
25 related health effects, but we do know that a tremendous

1 amount of malathion, for example, was used in Vietnam.

2 My understanding is, and I want to know if this
3 information is available, that apparently a fair amount of
4 pentochlorophenol was also used. Does anyone know any-
5 thing more about that? And also apparently maybe chlordane.

6 My question is: these chemicals are also known
7 to have certain types of adverse effects, and are these
8 going to be incorporated into this also? Or is it basically
9 going to be just herbicides? Or is it going to be more
10 topical chemicals that were used that may cause health
11 effects?

12 DR. STRIEGEL: Our current mandate is to address
13 the herbicides used in Vietnam--the 15 or so that I men-
14 tioned at the outset.

15 I think I have some literature that chlordane
16 and malathion at least were used in Vietnam in quantities.
17 They are not within our mandate at this time.

18 Dr. SHEPARD: May I amplify that?

19 This question, of course, has come up. As a
20 matter of fact it is in proposed legislation that the
21 epidemiological study as well as the literature analysis
22 be broadened in its scope to include other potential
23 chemical and environmental factors, to include the insecti-
24 cides, and some of the anti-malarial drugs that were used,
25 as well as other substances.

1 Our response to that to date has been that, as
2 far as the literature analysis is concerned, it was not
3 part of the original mandate of Public Law 96-151.

4 The contract for that effort has been awarded;
5 the work is well under way; and to interrupt that contract
6 at this point, to expand the scope of that contract, we
7 think would frustrate the efforts of that contract.

8 We think, however, that certainly the question
9 is germane, and we are currently considering the possibil-
10 ity of either negotiating an add-on contract, if you will,
11 or possibly a separate contract to study some of the
12 other potential problems.

13 DR. MOSES: Just to get this on the record, the
14 concern is that if pentochlorophenol was used, I don't
15 know how many people know that that also is contaminated
16 with dioxin, not the 2,3,7,8-TCDD but three other dioxins;
17 and that may or may not be important.

18 The other thing is there is some question now,
19 and maybe someone here knows, about the possibility, and
20 I understand there is controversy, regarding carcinogenicity
21 of malathion and mala oxon. And, chlordane is clearly a known animal
22 carcinogen.

23 So I think that that should also be appreciated
24 in the record.

25 Dr. SHEPARD: Thank you, Marion.

1 Any other questions from members of the
2 committee to Dr. Striegel?

3 [No response]

4 Mr.SHEPARD: Thank you very much, Jim;
5 we appreciate it.

6 DR. STRIEGEL: Certainly.

7 Dr.SHEPARD: The one thing that Jim
8 didn't mention, I don't think--maybe I missed it--is that
9 we anticipate the completion of his effort along towards
10 the end of September. We are very much looking forward
11 to that.

12 In response to the question on the news release,
13 we have copies of that, and Mr. Appleman assures me that
14 we will be getting more copies in a few minutes. This is
15 the news release on the signing of the contract for the
16 design of the epidemiological study.

17 DIOXIN CONFERENCE

18 Dr.SHEPARD: As I reported at the last
19 meeting, we are working towards holding a conference on
20 dioxins this October.

21 Some of you have already been provided copies
22 of the proposed agenda for that meeting, and we will
23 shortly have additional copies.

24 I just wanted to emphasize that we are moving
25 forward and will be very soon announcing this through

1 various professional journals and other opportunities for
2 disseminating this information.

3 We are very anxiously looking forward to this
4 conference. I think the way it has been put together and
5 the anticipated deliberations and reports that will come
6 out of this will make it a most exciting conference.

7 If, after you have had a chance to peruse the
8 agenda, you wish to address questions, and we have
9 additional copies of the agenda in a few minutes, we will
10 have some time for that later.

11 Dr. Suskind?

12 DR. SUSKIND: At the last meeting we talked
13 briefly about the sponsorship of this meeting. I am
14 wondering how that is going, and what your thoughts are
15 or the thoughts of the VA about it.

16 I was led to understand that this would not be
17 VA-sponsored, and that it would probably have sponsorship
18 by several professional societies with financial help from
19 the private sector.

20 Dr.SHEPARD: Well, I am not sure about the
21 latter point, Dr. Suskind. I think that we have not made
22 a final determination in terms of whom all the sponsoring
23 organizations should be.

24 We are not advertising it at the present time
25 as being a conference that will be sponsored by the

1 following organizations.

2 We have certainly solicited requests from various
3 organizations for participation: for proposed speakers,
4 comments on the agenda, and that kind of thing. So there
5 are a number of organizations that are interested in the
6 conference; but we have not solicited a list of sponsoring
7 organizations to date.

8 DR. SUSKIND: Putting on a conference like this
9 requires a fair amount of financial support, and I am
10 just wondering how you anticipate supporting the conference.

11 DR. SHEPARD: It will be supported largely
12 by registration fee, and we are looking to other sources
13 of financial support.

14 In the audience we have Dr. Richard Tucker.
15 Dick, do you want to just stand up?

16 Dick Tucker has worked very hard on this. He
17 represents SETAC, the Society of Environmental Toxicology
18 and Chemistry, and has been working with us and organizing
19 the meeting.

20 We have strong support from our colleagues in
21 Europe and countries in other areas of the world.
22 Dr. Otto Hutzinger, whom many of you know and who was
23 largely responsible for the Rome meeting, has worked very
24 closely with us.

25 We hope to have identified the key

26.

very soon
1 participants--the chairmen, if you will--of the various
2 sessions.

3 Dick, is there anything else you would like
4 to say?

5 Dr. TUCKER: No, nothing at this time.

6 Dr.SHEPARD: Again, if you have any
7 suggestions or recommendations please feel free to communi-
8 cate those to us.

9 Yes?

10 DR. KEARNEY: The Division of Pesticide Chemistry
11 of the American Chemical Society at Atlanta did want to
12 express their interest as being a co-sponsor here, and I
13 believe the Division of Environmental Chemistry has
14 expressed a similar desire.

15 Dr.SHEPARD: Very good. That is good
16 news. We had informal contacts with them, and we have
17 had that impression; but we are glad that it is now a
18 matter of record.

19 DR. KEARNEY: They are quoted now into that.

20 Dr. SHEPARD: Great. Thank you. That is
21 good news.

22 All right, let's now move on to the next item
23 on the agenda; namely a report from our service organiza-
24 tions.

25 At this point let me remind you that at the end

1 of the meeting we have designated some time for participa-
2 tion from the floor. If you have questions that you would
3 like to address either to the committee as a whole or to
4 individual members of the committee, Don Rosenblum has
5 cards.

6 If you just raise your hand, he will provide you
7 with cards on which to write questions and forward them
8 to me, and we will take them up at the end of the meeting.

9 At this time I would like to call on Dr.
10 FitzGerald, representing the American Legion.

11 REPORTS FROM VETERANS SERVICE ORGANIZATIONS

12 DR. FITZGERALD: Thank you, Dr. Shepard.

13 First of all, I would like to thank the VA for
14 carrying through on a previous suggestion that we made
15 about the playback to the individual veterans concerning
16 the information obtained from the health examination that
17 they had received at the VA.

18 I think that now the VA has provided each of the
19 hospitals with a form letter which goes out detailing the
20 information that was obtained on the individual examina-
21 tions.

22 I again caution the VA that diligence to be sure
23 that this is continued is of utmost importance.

24 Likewise, the question of the treatment of the
25 individuals' complaints, regardless of whether they have

1 any relationship to Agent Orange, at least the thing that
2 precipitates the individual coming to the Veterans Adminis-
3 tration is a specific complaint, and it is urgent that
4 these be paid attention to and be taken care of.

5 There is another difficulty that has arisen, and
6 that is that individuals who approach the VA for an examin-
7 ation for Agent Orange are not knowledgeable in many cases
8 as to the mechanics of the Veterans Administration.

9 They interpret the fact that they make an
10 appearance at the Veterans Administration as a simultaneous
11 formal claim of compensation. This, of course, is not
12 true.

13 I would suggest that the medical administration
14 personnel who first interrogate these people clarify this
15 with the individuals and make arrangements, if they so
16 desire, to follow through with the Department of Veterans
17 Benefits.

18 I think that is all I have at this time.

19 QUESTION & ANSWER SESSION

20 Dr.SHEPARD: Thank you very much, Dr.

21 FitzGerald.

22 In regard to your latter comment, you and I
23 talked on the phone the other day about that point e
24 have already set in motion a series of inputs into confer-
25 ence calls, alerting all our health care facilities to

1 that point and making the strong point that the initial
2 contact person in the medical administration services at
3 each of our facilities make it very clear to anybody coming
4 in for an Agent Orange examination that this does not
5 constitute a claim for disability, but that there is a
6 separate process for that.

7 So we certainly appreciate your comments and
8 your excellent suggestions, and we will take them into
9 consideration and implement them.

10 Are there any questions from members of the
11 committee to Dr. FitzGerald?

12 [No response]

13 Dr. SHEPARD: Thank you very much.

14 I would next like to call on Mr. Robert Lenham
15 for his comments.

16 MR. LENHAM: Thank you. I would like to agree
17 with the comments that Dr. FitzGerald has just made.

18 I would also like to express from an organiza-
19 tional standpoint the delight in knowing now that a design
20 study contract has been awarded. I think that it is going
21 to be helpful when we can go to the veterans and let them
22 know that progress, although it might be slow, is being
23 made and that a design study contract has been awarded, and
24 we can give them some knowledge and some input on what
25 might happen in the future as far as a timetable.

1 We have seen somewhat of a decrease in the
2 number of inquiries that are being made by veterans, and
3 this may be in part because they know that answers just
4 aren't available right now; and, as such, maybe they are
5 thinking--and this is speculative--that we will wait
6 until we can go in and maybe gain some positive results
7 from, say, an examination, or maybe a claim for disability,
8 et cetera.

9 From an organizational standpoint, I know
10 specifically from our National Service Offices, we have
11 noted a decrease.

12 The concerns that we still see coming in by and
13 large are related to the issue of birth defects, and
14 certainly we will be interested in receiving, when it is
15 available to us, Dr. Erickson's research on that issue.

16 We are pleased about the progress, again, that
17 the VA is making, particularly with the award for this
18 design study.

19 Dr. SHEPARD: Thank you very much. Mr.
20 Lenham represents the Disabled American Veterans, and we are
21 always happy to / ^{hear from} service organizations' representa-
22 tives. We consider these inputs as key to our operations.

23 I think this is one of the features that makes
24 this committee rather unique from other deliberative
25 groups, because we do have a broad input participation,

1 for which we are very appreciative.

2 In regard to the birth defects we are very
3 sorry that Dr. Erickson couldn't be here today. He was
4 planning to be here, but at the last minute he had to cancel
5 because of other pressing duties, and I gather they
6 are related to the TCDD study.

7 I think that what has happened is that there are
8 a number of contracts out for the administration of their
9 questionnaire.

10 I can tell you that his absence here does not
11 reflect any lack of enthusiasm on his part. I talk to
12 him frequently, and it is my understanding that they are
13 well along in having designed their questionnaire, and the
14 questionnaire and the study protocol is currently at OMB
15 for review.

16 I think I am correct in stating that they anti-
17 cipate starting up the administration of their questionnaire
18 sometime in the early fall.

19 So that effort is ongoing, and although we won't
20 have answers from it in the very near future I think that
21 the answers that we do get should be a great help in our
22 deliberations.

23 QUESTION & ANSWER SESSION

24 Dr.SHEPARD: Are there any questions?

25 [No response]

1 Dr. SHEPARD: Thank you, Bob.

2 Now I would like to call on Mr. Fred Mullen from
3 the Veterans of Foreign Wars.

4 MR. MULLEN: Thank you very much, Dr. Shepard.

5 In picking up on Mr. Lenham's statement regarding
6 the decrease in the amount of claims that are coming in,
7 I believe this might be a result of the negative results
8 of the studies on Agent Orange alone that have been coming
9 out.

10 Being faced with this type of information, a lot
11 of veterans just throw up their hands in disgust, and they
12 won't pursue.

13 The JRB study, broadening the scope of the
14 herbicide picture and not limiting it to only dioxin or
15 to Agent Orange, may affect an increase in the number of
16 claims coming in simply because there is some factual evidence
17 that some of the other herbicides that were sprayed are
18 carcinogenic, teratogenic, mutagenic.

19 In particular I am referring to the arsenicals.
20 Now, we talked a little bit about Agent Blue in the last
21 meeting, and following that meeting I did some hunting
22 around and found a 1977 National Academy of Sciences study
23 conducted on arsenic.

24 One of the recommendations of that study was that
25 someone pick up the ball and carry it regarding the

1 in vivo change of organic arsenicals to inorganic state.

2 Another thing that I found out was that a lot of
3 the studies that had been conducted with arsenic were con-
4 ducted with rats, which were the least likely to yield any
5 favorable information.

6 Now I am glad to see that Dr. Striegel is getting
7 into the cacodylic acid research, and I'm wondering if
8 that is going to be part of the UCLA study.

9 Dr. SHEPARD: I certainly would think so,
10 yes.

11 As you know, Public Law 96-151
12 mandates we focused on the phenoxy herbicides. It is
13 pretty evident, at the present time, that other
14 than the Ranch Hand study, in which the exposure data is
15 well documented and was pretty much confined to phenoxy
16 herbicides, we will not be able to identify with great
17 surety ground troops who were specifically exposed, and to
18 what extent.

19 So I think of necessity any epidemiological study
20 of troops in Vietnam will have to include other exposure
21 factors.

22 We are certainly looking into this, and, again,
23 we have been asked this question many times both by the
24 general public and by members of Congress, and we have
25 testified to various Congressional committees on this point.

1 As you probably know, there are a number of pieces
2 of legislation, as I indicated, that would mandate the
3 broadening of the scope of the epidemiological study. Our
4 standard answer is that we agree with the science panel of
5 the Interagency Work Group that it is going to be difficult
6 if not impossible, to establish with certainty which ground
7 troops were exposed to phenoxv herbicides.

8 But we think that until we have our contractor
9 aboard and he has had the opportunity to review the data
10 sources, that we should not make a judgement. We
11 should let the contractor be the one to make the judgement
12 on the subject of exposure data and how it bears on the
13 epidemiological study.

14 MR. MULLEN: Dr. Shepard, I would like to bring
15 up one more point, and that is regarding identification of
16 those persons who may have been exposed.

17 The Agent Blue was used almost 50-50 on cereal
18 grain destruction. The other 50 percent was used solely
19 on base perimeters for a zone of fire.

20 So every ground troop in Vietnam has been exposed
21 to that chemical. And more often than not the area
22 sprayed had listening posts, outposts with the foxholes
23 you sat in, and they were damp or had water in them, and they
24 certainly had Agent Blue in them.

25 Dr. Moses has just made a little note to me here.

1 DR. MOSES: If I had known you were going to say
2 it I wouldn't have made it a note.

3 [Laughter]

4 MR. MULLEN: Well, just to add a little levity,
5 maybe we should start looking for those Vietnam veterans
6 who are now hippies. You say you can't find arsenic in
7 the hair after it has been cut.

8 If we round up some of these hippies, I am sure
9 that in the ones with the long hair we will find some
10 positive results.

11 [Laughter]

12 Dr. SHEPARD: Yes, Dr. Lingeman?

13 DR. LINGEMAN: / ^{Concerning} comments about the carcino-
14 genicity of arsenic or and other toxic effects in ~~many~~ Arsenic has
15 been known for some time to cause a relatively specific
16 type of skin lesion--a precancerous skin lesion--known as
17 Bowen's Disease. Pathologists are very capable of
18 recognizing this.

19 Now in the Registry of the AFIP, so far, we have
20 not seen any Bowenoid skin lesion in Vietnam veterans.

21 We will be looking for this, because we have been
22 alerted to the fact that this lesion is associated with
23 chronic arsenic intoxication, most of which has followed
24 medications with arsenical compounds such as Fowler's solution.

25 Some of the people at the AFIP, Drs. Graham and

1 Helwig of the Dermopathology Department there, did some
2 work on this several years ago and actually
3 found that there were excessive levels of arsenic in the
4 Bowenoid skin lesions themselves.

5 So the AFIP is not only prepared to diagnose
6 this Bowenoid lesion, but also to measure
7 the arsenic levels in the lesions.

8 Because the hair grows out, I think
9 the skin might be a
10 better place to look for it.

11 Dr. SHEPARD: Dr. Suskind?

12 DR. SUSKIND: On the troublesome subject of
13 arsenic I think the record should be set straight.

14 To my knowledge organic arsenic, of which
15 cacodylate is an example, has not been known to cause
16 kerotoses, pre-cancerous or otherwise, or squemacell
17 carcinomas.

18 This is largely the result of either ingestion
19 or inhalation per cutaneous absorption of inorganic
20 arsenic.

21 The orcharders in the Northwest are susceptible
22 to it because they use lead arsenic.

23 When Fowler's Solution was commonly used, and
24 in some instances it is still used, some people who were
25 taking it developed kerotoses and some of them developed

1 squemacell carcinomas.

2 I am old enough to have seen a fair number of
3 those, because arsenic during my days at medical school
4 was still used.

5 I think that one also has to recognize that the
6 arsenic does not stay in the horny layer, whether it is
7 the horny layer of the skin or the hair; because the hair
8 grows and it grows out, and there is no locus of arsenic
9 after the hair grows out. There is no locus of arsenic
10 in the skin with the normal desclimation of the horny
11 layer.

12 So even in Bowen's Disease you don't find arsenic
13 in the Bowen's lesions a long time after the arsenic has
14 been ingested. I believe this is fairly well known. One
15 wouldn't expect to find it because the arsenic doesn't
16 remain in the skin, but the effect of the arsenic is still
17 in.

18 May I change the subject?

19 Dr. SHEPARD: Certainly.

20 DR. SUSKIND: I am interested to hear that there
21 is a decrease in complaints. I believe that the decrease
22 in complaints is due to a variety of things, among them
23 are factors that have already been mentioned.

24 I feel strongly, however, that in local areas
25 a great deal of help, especially about the anxiety relating

1 to health problems, has been provided by the storefront
2 VA counseling services.

3 They have been of enormous help, and I find it
4 rather difficult to understand why the support for such
5 services is to be decreased or even discontinued.

6 I would like to ask what the position of the
7 three veterans groups is about this very, very useful
8 service.

9 DR. FITZGERALD: I would be glad to address that,
10 Dr. Suskind.

11 The American Legion has been on record as sup-
12 porting, at least for another two years, the continuation
13 of the storefront activities.

14 We recognize what you are saying, that they have
15 served a purpose beyond what they were originally intended
16 for.

17 Indeed, they have come to be looked upon by the
18 public as identical with the problems of Vietnam veterans,
19 and this may or may not be true but nevertheless it is a
20 fact of life.

21 I would like to magnify what you have surfaced
22 as far as the anxiety is concerned. I think that this is
23 a very real situation at the moment, and it gives me the
24 greatest of concern as far as the individual veterans are
25 concerned, primarily from the news media putting out of

1 proportion the information that is currently available on
2 Agent Orange.

3 Whether, indeed, we come up with a positive
4 effect of Agent Orange on other diseases in the future,
5 all of us are keeping an open mind; but to the uninitiated,
6 at the moment, this has proved to be a present problem.

7 I will give you specific examples: The fear of
8 having deformed children is primarily the one that comes
9 out most frequently.

10 Individuals who are having spermatic cord
11 ligations simply because they are afraid of siring disabled
12 children -- this is how real it is in the veteran popula-
13 tion that is just reading the media.

14 MR. LENHAM: I would like to add to that from
15 the DAV. We have testified both before the House and the
16 Senate subcommittees that this program, the Vet Centers,
17 needs to continue.

18 It is doing the job that it was set out to do,
19 and more. That was to specifically deal with the Vietnam
20 veteran and the enormous problems that have been given to
21 him as the result of an involvement in a very unpopular
22 war.

23 We have over 70 outreach centers that are in
24 existence and were in existence prior to the Vet Center
25 coming about. Together we have worked hand-in-hand, and we

1 will continue to do so.

2 It is an avenue and a tool that is working, and
3 to even entertain the thought of throwing that tool away
4 would be of extreme detriment to a veteran population; not
5 only to the veteran but to his family members as well,
6 because they share the same concerns. I think we need to
7 recognize that.

8 Dr.SHEPARD: Fred?

9 MR. MULLEN: I agree with both Dr. FitzGerald and
10 Mr. Lenham. I would like to also say that at present the
11 VA is not geared toward genetic counseling or family
12 planning, and I think that this should be looked into.

13 These veterans who have, for physical or
14 psychological reasons, been afraid to sire or who have
15 sired deformed children, we believe that they should be
16 supplied fee-basis genetic counseling by the Veterans
17 Administration.

18 We believe this should be done because by the
19 time we find out that herbicides do or do not cause this
20 problem the damage will already have been done, and we
21 believe the counseling has to be provided now rather than
22 waiting for an answer to that one particular question.

23 Dr.SHEPARD: Let me just respond, too.

24 As you know, this has been a source of consider-
25 able Congressional interest. In hearings that have been

1 held over the past few weeks the issue of the outreach
2 program, the so-called "Readjustment Counseling Program",
3 has been brought to the forefront.

4 I was involved in/ ^{hearings of} the Senate Veterans
5 Affairs Committee last week, in which a
6 considerable amount of time was devoted to this specific
7 issue.

8 I may lose my job if I say this, but I'll say
9 it anyway: I think it is safe to say that there are a
10 significant number of individuals within the Veterans
11 Administration who would like very much to see this program
12 continue.

13 It was an OMB decision. Since we all are
14 members of the executive branch of the Government, obviously
15 we have to be guided by the decisions of the Office of
16 Management and Budget.

17 However the Congressional interest has been to
18 such an extent that I am moderately hopeful that that
19 decision may undergo some revision. The outcome may in
20 fact be that for the near term, at least, the Readjustment
21 Counseling Program will be continued.

22 DR. SUSKIND: I don't think it would be inappro-
23 priate then that this committee, as an advisory committee
24 to the / ^{Veterans} Administration, go on record in the support of
25 the continuation of the counseling services. I so move.

1 Dr. SHEPARD: I think it is an entirely
2 appropriate move, Dr. Suskind, and I am sorry Dr. Crawford
3 isn't here. He was here earlier. I am sure that he would
4 be most gratified to hear your comments of support.

5 If that is the will of the committee, we will
6 enter into the record that the committee strongly supports
7 the continuation of the Readjustment Counseling Program,
8 and we will make this known to the Administrator and
9 other interested groups.

10 Unless I hear some dissension to that position,
11 we will make that a matter of record.

12 Thank you, sir.

13 QUESTION & ANSWER SESSION

14 Dr. SHEPARD: Are there any other comments
15 or questions for our service organization representatives?

16 DR. KEARNEY: Just one question: Can anyone give
17 me more information about the proposed meeting on Agent
18 Orange at Washington University? Does anyone have any
19 information on this?

20 MR. FURST: It is Memorial Day weekend.
21 The 22nd through the 24th of May. Friday, Saturday and
22 Sunday.

23 DR. Kearney : Thank you.

24 Dr SHEPARD: Jon Furst from the National
25 Veterans Task Force on Agent Orange is in the audience, and

1 during our discussion period I hope that Jon will provide
2 us with some information. It is largely through his
3 efforts that this symposium is being organized, and I hope
4 we will have some time to discuss the details.

5 DR. KEARNEY: Thank you.

6 REPORTS FROM STATE GOVERNMENTS

7 Dr. SHEPARD: Over the last year I have been
8 impressed by the amount of attention that various State
9 organizations have developed regarding Agent Orange.

10 I have tasked our office to be kind of a
11 clearinghouse of information for State organizations. Some
12 States have actually had legislative enactments establish-
13 ing Agent Orange commissions, and this has taken on a
14 variety of efforts.

15 I am pleased now to recognize two State organ-
16 izations who have representatives here today; namely the
17 State of New Jersey and the State of Wisconsin.

18 There are other States which have become organ-
19 ized. The State of New York has a dioxin exposure Commis-
20 sion. Dr. Peter Greenwald, who directs the Department of
21 Epidemiology in the State of New York Department of
22 Health, will be in my office this afternoon, and we are
23 going to have a dialogue among the various State organiza-
24 tions.

25 We will attempt to share information and

1 bring each other up-to-date as to where they stand, and we
2 will attempt to be of mutual help.

3 I would like at this time to call on Mr. Wayne
4 Wilson from the State of New Jersey Agent Orange Commission
5 so that he can give us an update.

6 With him is Dr. Peter Kahn, also with the New
7 Jersey Agent Orange Commission.

8 Wayne? It's good to see you.

9 I had the privilege of attending one of their
10 meetings, and I'm very grateful to see them here.

11 MR. WILSON: My name is Wayne Wilson, and I am
12 the Executive Director of the New Jersey Agent Orange
13 Commission.

14 I left the house at 3:00 this morning, so you
15 will have to bear with me a little bit, okay?

16 First off, New Jersey was the first State in
17 the nation to establish a State Commission with a defini-
18 tive legislative mandate.

19 I think primarily our mandate calls for us to
20 do three primary things. Those three areas include
21 providing direct counseling, legal assistance, and out-
22 reach efforts to veterans. We are also mandated to gather
23 various types of data and to examine closely the possibil-
24 ity of doing a number of studies.

25 Possibly Dr. Kahn may be able to discuss

1 briefly some of that work.

2 Our seven commission members are unsalaried.
3 By law four must be Vietnam veterans, and they are. The
4 other three primarily come from the medical and scientific
5 fields.

6 I did not prepare any remarks this morning,
7 because I wanted to take this opportunity to kind of tell
8 you like it is, very briefly.

9 We are using, in terms of outreach activities,
10 six Veterans Administration facilities, primarily for the
11 purpose of having Agent Orange screening examinations
12 done.

13 I would not go around the State of New Jersey
14 without coming here and saying the exact same thing that
15 I say across the State. We have done approximately 30 to
16 40 programs and have talked to and listened to thousands
17 of Vietnam veterans and their families.

18 Frankly, as I sit here, I am critical of the
19 Veterans Administration; and I am not at all sure that
20 everyone senses the urgency that the thousands of veterans
21 and their families have communicated to us.

22 I think that is very important, because I think
23 that's what it's all about. We have found within the six
24 area VA facilities we use, many, many inconsistencies.

25 I do not share some of the comments made by some

1 of the veterans representatives here that this business
2 has peaked or is on the decline.

3 I think that veterans are frustrated at where
4 they can turn for help and assistance, and I mean immediate
5 help.

6 If you will go to New Jersey you will see
7 wherever there is an organized effort to serve the veteran,
8 specifically in terms of Agent Orange, you will find large
9 numbers of claims being placed, larger numbers of people
10 requesting information, assistance and examinations.

11 I think the veterans and their families are
12 looking for facts. Mr. Cleland described this as a dirty
13 little cold book that will help allay the fears of Vietnam
14 veterans. It does not.

15 I don't think that benefits counseling should
16 be done by medical service administrators or doctors. Most
17 veterans, when they get their Agent Orange examination, hit
18 the bricks wondering what happened.

19 Some of the things that have been said here this
20 morning are not what we are finding in talking to thousands
21 of veterans, not only in New Jersey but in Pennsylvania and
22 Delaware.

23 For example, I think Dr. FitzGerald said that
24 each veteran who is examined now receives a form letter
25 detailing the exam results.

1 Let me tell you that the East Orange Veterans
2 Administration Hospital provides a four-lined form letter
3 that says, "Your tests were within normal limits." There
4 are no details of the examination results.

5 In fact the East Orange Veterans Administration
6 Hospital is sending letters to veterans which say, "We
7 have noted minor abnormalities. Please consult your
8 personal physician."

9 We say to East Orange, "Why are you telling
10 veterans to consult their personal physicians?"

11 They tell us, "No service connection has ever
12 been substantiated," and therefore there is nothing they
13 can do.

14 One other thing. We met last week with repre-
15 sentatives of the East Orange VA Hospital, prior to coming
16 down here, to see if we could clearly set up some proce-
17 dures and possibly help them from taking the bad rap that
18 they do take.

19 I don't think that we were successful. Among the
20 suggestions that we made was to possibly take a GS-3 or a
21 GS-4 clerk who, as a last contact with the veteran, could
22 just ask that veteran, "How did it go? Do you have any
23 questions?"

24 They told us that they didn't think they could
25 find anyone in the hospital good enough to do that job.

1 East Orange Hospital at the present time is
2 allowing our commission to schedule four examinations a
3 week. Four.

4 We estimate that with an estimated 56,000
5 veterans in the State of New Jersey it will take them
6 267 years to completely examine all of our people.

7 We have asked for an increase. Now they will
8 allow us, as of last week, to do six per week. And for
9 good measure they will throw in a group from one of the
10 veterans organizations on one Saturday a month.

11 Veterans know that every VA medical center is
12 doing their own thing. And as one VA administrator told
13 me, "We are allowed to bend the rules."

14 Now, time won't permit me to go into all of the
15 details; but I come here as an executive director of a
16 program, and I am telling you what veterans are telling me.

17 They are frustrated. They do not perceive the
18 Veterans Administration as caring about their medical
19 problems, specifically Agent Orange.

20 I am not a scientist, I am not a physician, I am
21 not a lawyer; but I am a Vietnam veteran, and I hear my
22 fellow Vietnam veterans.

23 They cannot come here. But if they could they
24 would communicate to each and every one of you what they
25 feel in their hearts about the problem of Agent Orange.

1 I don't think it should be dismissed. I think
2 there is an urgency to get on with doing what has to be done.

3 I read the official transcripts that come out of
4 these meetings, and I have forwarded to Mr. Young and Mr.
5 Sommer from the American Legion what we feel are questions
6 that have not been answered.

7 All too often things run -- I can't believe the
8 timetable. For example, the literature analysis--it's
9 way behind.

10 I asked the Department of the Army what their
11 policy was on Agent Orange. They sent me a January 2,
12 1979 memo that grossly understates the problem.

13 We have large numbers of active-duty personnel
14 in New Jersey, and they don't know where to turn for help.

15 Speaking of VA outreach centers, we had a call
16 from a woman whose husband has tried to commit suicide
17 three times. She sought our assistance, and we referred
18 them to the Philadelphia Vets Center. When I called the
19 team leader he said, "Wayne, I'm sorry; he's got three
20 ahead of him today." And two outreach centers, one in
21 Newark and one in Jersey City, will not get it for the
22 State of New Jersey.

23 I don't know how many of you folks out here have
24 been in one of those VA outreach centers, but I have.
25 They are not situated in very swank places in the city, but

1 they have seen over 52,000 Vietnam veterans. I don't know
2 how many had long hair or not, that's not important to me.

3 I would advise you, and I would encourage you,
4 and I would even challenge you to come on up to New Jersey
5 and spend a day with us, and really talk to the Vietnam
6 veteran and his family and hear what they say and feel what
7 they say, and hopefully care about what they say.

8 That's all I have to say. Thank you very much.

9 [Applause]

10 DR. SHEPARD: Peter, do you want to give
11 us a progress report?

12 Let me just say that we will be meeting with
13 Wayne and Peter this afternoon, hopefully, and we will
14 go into more detail.

15 I certainly would like to say right now, Wayne,
16 that I appreciate your input, and I will hope to redouble
17 our efforts to try to resolve some of these problems.

18 DR. KAHN: Thank you.

19 I want to reinforce the sense of urgency that one
20 gets in speaking in the field, as Wayne says, to literally
21 thousands of veterans.

22 The commission organizes programs at the rate of
23 a couple of week, frequently. I often go to these, as
24 one of the scientific members of it, where, free from the
25 hysteria of the popular press, I try to present what little

1 bit is known about the toxic and potentially toxic effects
2 of herbicides.

3 Even though Wayne keeps trying to make me speak
4 for less and less time at each meeting, that never seems
5 to work, because we always get flooded with questions.

6 Often they are of an intimate, personal nature
7 which people are so concerned about that they will stand
8 up in a public meeting of a couple of hundred and present
9 their intimate personal problems. It takes a certain
10 amount of concern for someone to put up with the embarrass-
11 ment that comes with such a presentation.

12 I get phone calls in my laboratory. I have a
13 string of messages every day. How they found my office
14 number I don't know, but nevertheless I get flooded with
15 calls. I try to answer every one, which means that I am
16 going to wake up with a long black thing growing out of my
17 ear one day.

18 But that sense of urgency is really out there,
19 and it is particularly out there among people who have
20 had relatively few medical problems and who see things
21 coming at them now that they fear might be due to Agent
22 Orange.

23 It comes also from people who are perfectly
24 healthy but who fear, as one of the earlier speakers
25 mentioned, that there would be a problem in the fathering

1 of children.

2 It comes across not just as a scientific issue,
3 something that I will one day write about,

4 but it comes across as human beings
5 with whom you sit down and drink a beer. And they are
6 worried.

7 At Saddle Brook, in Northern New Jersey a couple
8 of months ago, we had one of these programs to about 250
9 people in the VFW Hall.

10 One of the men there, who was a Korean War
11 veteran and who had never been to Vietnam, said that if
12 another war were to come that he would take his family to
13 Canada.

14 I then asked the group there, based on their
15 own experiences, whether they would send their sons into
16 the service. You could hear a pin drop in that room. And
17 these are men who served in World War II, in Korea, and
18 in Vietnam. We had veterans of all three wars present.

19 The message is loud and clear: The Government
20 is perceived as treating shabbily those who fought the last
21 war. And as long as it is so perceived, who will you get
22 to fight the next one?

23 Now the matter of the science involved in this
24 comes up, because I present to the veterans at these talks
25 what the commission is attempting to do with minimal

1 resources.

2 difficult
3 And there is nothing/in the science to be done
4 about finding out whether there is or is not a definite
5 connection between Agent Orange and subsequent medical
6 problems. There is nothing in that science that is beyond
7 the comprehension of anybody who can read a newspaper.

8 It may take a little time to explain it. You may
9 have to explain some words of four and five syllables that
10 are not in common use; but if one is willing to take that
11 time and make those explanations everybody out there can
12 understand what we are about.

13 And I do that. And they strongly want the work
14 to be done as quickly and as expeditiously as possible.

15 Now, in poking about, looking for expertise that
16 I don't have in epidemiology and toxicology, and so forth,
17 I have gone about talking to colleagues who have that
18 expertise.

19 I am finding out that vast resources are not
20 needed to do the necessary work. One needs some, but you
21 don't need millions and millions of dollars.

22 There are many, many potent scientific questions
23 that can be asked of existing records, and I don't see
24 that work being done, and our commission is picking up on
25 some of it.

 In that connection the Veterans Administration

1 has been kind enough to tell us that they will make avail-
2 able over the next several months a computer tape--or a
3 series of three, actually--which will give us the names and
4 addresses and perhaps some other information about New
5 Jersey veterans of the Vietnam era.

6 We have been trying since last July to get that
7 information. We don't have it yet. We do have the promise
8 that it will be forthcoming in the next several months.

9 It has taken great pressure to spring that informa-
10 tion loose.

11 A variety of arguments have been given against
12 making that information available to us. They all smack
13 to us of bureaucratic foot-dragging.

14 Now that the information is to be made available
15 to us, we are told that there are restrictions on its use.
16 It may only be used to "aid in the filing of claims and
17 to dispense information concerning Agent Orange. It may
18 not be used for research purposes."

19 I find it incomprehensible as a scientist as to
20 why the use of the names and addresses of New Jersey
21 veterans for the research purposes mandated by law in the
22 commission's setting up -- as to why we can't do that.

23 We are not about to go and do things to which the
24 veterans do not give consent. If a man is asked to parti-
25 cipate in any kind of a study, he is asked to give his

1 full formal consent to go in and spend a boring Saturday
2 filling out a form in the company of somebody who knows
3 what it is all about.

4 And if a man is willing to do that, knowing he
5 is blowing a nice Saturday afternoon to do it, I certainly
6 think we should be empowered to ask him if he is willing
7 to do that.

8 You know, when people tell me I can't do obvious,
9 simple, sensible research that the veterans themselves
10 say they want done, I get a little hot under the collar,
11 and I think suitable pressure from this committee might
12 help us release that restriction.

13 DR. SHEPARD: Thank you. It's news to me.

14 DR. KAHN: I wanted to get that on the record.
15 I figured it was news to you. I didn't think you would be
16 a party to anything like that.

17 DR. SHEPARD: Believe me, we will certainly
18 search out the facts behind that. I was not aware that
19 there was any restriction being placed on tapes. It is not
20 the purview of our office to make these decisions; that's
21 why it is news to me.

22 DR. KAHN: I know that, but I just wanted to
23 apply pressure.

24 DR. SHEPARD: I'm glad you brought it up,
25 and hopefully in our meeting this afternoon we will have

1 somebody there who will be able to answer that question.

2 Yes, Marion?

3 QUESTION & ANSWER SESSION

4 DR. MOSES: I would like to ask Mr. Wilson
5 a question.

6 What do you feel is the greatest need, in terms
7 of your presentation, for more of these psychological
8 testings? Or do you think there is more need to do physical
9 examinations?

10 I realize the needs are great, and it varies, but
11 what do you see in terms of New Jersey as the greatest
12 need right now that your commission needs help with, in
13 terms of directly helping a veteran?

14 MR. WILSON: We need the availability of Veterans
15 Administration resources.

16 In terms of psychological counseling we know,
17 for example, that many veterans who go in for Agent Orange
18 examinations will end up, as part of that process, in
19 seeing someone in NNP--a psychologist or a psychiatric
20 person.

21 Let me give you an example. A veteran went into
22 East Orange Hospital for an Agent Orange examination on
23 December 8, 1980, reporting severe skin eruptions on major
24 portions of his body that were interfering with his employ-
25 ment as a mailman.

1 He was examined and was rescheduled for a follow-
2 up examination on May 7, 1981--five months to have a derma-
3 tologist look at what the man reported to be a severe
4 problem.

5 We were told that East Orange only has a part-
6 time dermatologist consultant come in one afternoon a week.
7 That is completely unsatisfactory since I assume most
8 people know that many veterans, whether it is chloracne
9 or regardless of what it is, are reporting a number of
10 skin problems associated possibly with their service in
11 Vietnam.

12 It would only seem reasonable to me to have
13 provisions made so that we don't make a person wait five
14 months.

15 That veteran, in our survey, said, "I don't
16 believe it." And I didn't believe it either, until I,
17 in fact, wrote the director.

18 DR. MOSES: But do you think this should come
19 through the Veterans Administration? You are not recom-
20 mending that they should go to dermatologists and send the
21 bill to the VA, are you?

22 MR. WILSON: I think the Veterans Administration
23 should make available the resources and the personnel and
24 the money to get the job done in terms of Agent Orange
25 screen exams. If you are not going to do it, then you

1 might as well stop telling veterans you will examine them
2 for nothing.

3 Because, I'll tell you, four exams a week -- we
4 are not getting anywhere that way. And I think we have to
5 be realistic, and we are not being realistic.

6 When you tell a veteran--we are booked up now
7 until July at the rate of four a week--that he has to wait
8 until July or August to be examined, he doesn't perceive
9 the Government as really concerned.

10 DR. KAHN: Could I field this question?

11 DR. SHEPARD: Yes, though we are going to
12 have to move along.

13 I just want to interject that this is the first
14 time I have heard this problem about East Orange. I'm not
15 suggesting it's not entirely practical, but I would have
16 hoped that Wayne would have brought it to my attention
17 earlier so that we could have done something about it.

18 That is the sort of thing I can do something
19 about.

20 DR. MOSES: I can tell you of another VA Hospital
21 who only has a dermatologist one day a week.

22 MR. WILSON: Don't hold me to just East Orange.
23 It's just East Orange today.

24 DR. SHEPARD: I just cite East Orange as
25 an example of ways in which we should keep our lines of

1 communication open, because that is an area where I can
2 be of help.

3 I can also assure the committee and the audience
4 that it is the Veterans Administration's goal that no unreasonable
5 of period /waiting time be imposed on the veteran who
6 is requesting an Agent Orange examination. That is our goal;
7 now, whether that is the way it is carried out universally,
8 I can't of course answer that. But it is our hope that
9 that is the case in the majority of instances.

10 DR. SUSKIND: I think that this discussion is
11 really very helpful to the members of the committee who
12 don't know what is really happening in any boondocks except
13 their own.

14 My experience with the VA Hospital in Cincinnati
15 is very different from your experience at the VA Hospital
16 at East Orange.

17 Perhaps the reason for it is that it is univer-
18 sity associated and fully staffed with dermatologists,
19 pulmonary people, toxicologists, and so on.

20 So I think it is a matter of the availability
21 of the resources.

22 I was interested in hearing one comment by Dr.
23 Kahn, and I wondered if he might answer a question about
24 it.

25 Can you give me an example of what scientific

1 questions can be answered easily, as that is what you said.

2 DR. KAHN: Yes.

3 You ask the question first as to whether a
4 larger number of Vietnam veterans have died than one would
5 expect in similar economic, age, demographic circumstances.

6 New Jersey maintains a computerized registry
7 of death certificates which contains some information that
8 is written on the death certificates. It also contains an
9 access number by means of which the death certificate can
10 be pulled from a paper file.

11 It also has a fairly slick operation in terms of
12 computer programming that permits you to probe those death
13 record files.

14 I presume that most of the States have similar
15 arrangements, although no two will be identical.

16 It is not very expensive to do this, and our
17 preliminary look at it at the moment--we are going to do
18 such a survey--looks as though it is going to cost us
19 between \$2 and \$2 & 1/2 per death record that we search.
20 Okay? And the State Government will make available the
21 funds to do that.

22 Now, this is something which is quite circum-
23 spect. On the death records there are causes of death
24 listed, and States here vary on the practice that they use
25 in tabulating such information.

1 In New Jersey the final cause of death is not
2 always what is put on the computerized search. What they
3 put in is the principal cause.

4 So for a fellow who expires of pneumonia brought
5 on as a result of cancer, what will be listed is "cancer"
6 and not the pneumonia. So at least they are a leg up on
7 practices in some places.

8 We are going to do such a search. It is not
9 going to cost us a lot of money. So there is one thing
10 we can do.

11 Another one: The State has begun setting up
12 and has just about got operational a tumor registry. In
13 it, at the moment, are all tumors that have been diagnosed
14 in the State of New Jersey since October of 1978.

15 Now the progress of cancer being what it is,
16 most of those people are still alive. And so, one can
17 ask the question--if somebody finds his way into the tumor
18 registry, is he or is he not a Vietnam veteran? And is
19 the incidence of such things higher or lower than what
20 one would expect in persons of his or her age and other
21 circumstances?

22 These are just a couple of things that one can do.
23 I have a list of others.

24 DR. MOSES: It seems to me, though, that this
25 would depend on getting the names and addresses and getting

1 information from the Veterans Administration.

2 DR. KAHN: Square One.

3 DR. MOSES: Yes. I don't see how you could do
4 it without that.

5 DR. KAHN: Sure.

6 DR. SHEPARD: You are bringing up a good
7 point, Peter; but we are going to have to move along,
8 because we have gentlemen from Wisconsin with us.

9 But what you allude to in terms of a mortality
10 study is precisely something that we will discuss further
11 this afternoon when Dr. Peter Greenwald will be with us,
12 and that is something that we are doing with the State of
13 New York. So the opportunities are there, and we heartily
14 endorse those efforts; in fact, we are cooperating very
15 extensively.

16 So that is another puzzlement as far as why this
17 information is not usable.

18 Thank you.

19 Now, I call on Dr. Anderson and Don Laurin from
20 Wisconsin to tell us a little bit about their State
21 activities.

22 It is a great pleasure to have these gentlemen
23 with us today, and they will be meeting also with us this
24 afternoon.

25 DR. ANDERSON: Thank you very much. Both of us

1 are glad to have the opportunity to travel out here to the
2 East.

3 We have the same concerned veteran population
4 that you have heard about, and we have a very similar
5 type of reaction.

6 I would like to just spend a very brief time
7 outlining the history of our program and where we are at
8 today, and perhaps at another time with more time available
9 we can present some of our results when we get them
10 tabulated.

11 Back in 1979, I think along with the frustration
12 that you heard just before us, the State Legislature in
13 Wisconsin had a very vocal group of veteran constituents
14 and felt that they were quite frustrated with providing
15 them with adequate assistance.

16 So, beginning in June of 1980, they appropriated
17 \$124,000 to establish an outreach information identifica-
18 tion program.

19 This was to have several main goals. One was to
20 determine how many Vietnam veterans we had in the State,
21 and what their current perceived health problems were, and
22 what we could do to assess their impact on the State health
23 care delivery system.

24 One thing that we were very fortunate in was that
25 when the Selective Service was disbanded, the Department

1 of Veterans Affairs for the State was given custody of
2 the DD214 discharge papers for all of the veterans in the
3 State of Wisconsin.

4 Utilizing those some 200,000 records we were able
5 to handsort and select out all of the individuals with
6 the Southeast Asia Service Star, which all of the Vietnam
7 veterans received.

8 So we were somewhat fortunate in having a fairly
9 well-defined denominator population of 58,400 veterans
10 from Vietnam service.

11 This group, of course, does not include those
12 individuals who have since moved into the State, although
13 our program is directed at providing them information.

14 But our basic group of names that we use to send
15 out information to identify individuals came from this
16 58,400.

17 We also then began to develop educational mater-
18 ials. There was clearly a need in the State for people
19 to find out how they may have been exposed, what sorts of
20 problems have been associated, and where they could go
21 primarily for assistance.

22 This was primarily a young population, many of
23 whom did not have ready access or had not previously gotten
24 into the health care delivery system.

25 So when they became ill or they had questions

1 or problems; many of them did not have a private physician
2 that they went to on a routine basis, and we sensed that
3 there was some floundering on their behalf as to "How do
4 I get into that?"

5 Don can tell you a little bit more about the
6 various other organizations that we are working with; but
7 we perceive that one of our tasks, as your task here is,
8 is on a State basis to provide coordination and assistance
9 to the various organizations that are trying to assist the
10 veterans, and to work very closely with the State medical
11 association to identify individuals who could act as
12 resource persons for the veterans.

13 We also, of course, encouraged all of those to
14 get into the VA to be examined; but we did try to seek
15 alternate sources for those individuals who needed more
16 continuing care on a local basis.

17 So ours was very much of a coordinating activity.
18 We have been involved, especially Don, in developing slide
19 tape shows. We are in the process of putting together
20 with the WHA-TV, the public service television group in
21 Wisconsin, a television program, and we have had numerous
22 call-in radio programs.

23 We also run a hotline for information to the
24 vererans.

25 To date, with our last mailing having gone out

1 about a month ago, we have received out of that 58,400
2 some 30,000 returns. I think that speaks for the concern
3 in the community for a rather brief mailed-out informa-
4 tional sheet which we ask them to return.

5 You have to be aware that of course this goes
6 back to addresses from 1962, and some of these individuals
7 are deceased. So we feel our response rate is quite
8 respectable at this point with only having gone with a
9 mailing.

10 We of course are working very closely with the
11 Department of Veterans Affairs and their county service
12 officers who work with many of these individuals on a daily
13 basis and will also be providing input for us.

14 At this point, since we don't have all the
15 results in and we are a small program, the staff of which
16 you are seeing here --

17 [Laughter]

18 DR. ANDERSON: -- I think you can appreciate the
19 magnitude of the response; but I am happy to say that by
20 the end of June we will have all the information in, and
21 we will begin to come out with some of the summary statistic
22 information.

23 Yet, as I say, we ask some very simple questions.
24 It was perceived health problems--and I stress the
25 "perceived."

1 20 percent said that they would be very much interested
2 in participating in a more-detailed study or investigation;
3 again, showing the concern that these veterans have and
4 their interest in the problem.

5 I think, at this point, that gives you the basic
6 background of our program, and I would like Don to speak
7 for three to five minutes, as we were told, on his exper-
8 ience with the hotline in dealing with the veterans.

9 MR. LAURIN: First of all I would like to say
10 that the gentleman from New Jersey expressed a sentiment
11 that I have been hearing from the veterans in the State
12 of Wisconsin.

13 There is a lot of concern and anxiety among the
14 Vietnam veterans, their families, and their wives, that
15 their problems may be due to Agent Orange exposure.

16 We were lucky in Wisconsin that we had a list
17 already available to us of the Vietnam veterans. Because
18 of that we have been able, as Dr. Anderson mentioned, to
19 send this questionnaire out to 58,000 veterans.

20 I think that when we get done compiling all the
21 data we will find out that we have over 60 percent response
22 rate from our survey. I think this is excellent.

23 It also shows the concern that the veterans in
24 Wisconsin have.

25 We have also sent out over 40,000 of these

1 brochures which we had printed up called "Questions and
2 Answers About Agent Orange." We are printing another 40-
3 or 50,000, and they will also be distributed around the
4 State.

5 In Wisconsin we also have a very good network
6 of veterans organizations. We work very closely with the
7 Veterans of Foreign Wars, the American Legion, Order of
8 Purple Hearts, Vietnam Veterans Against the War, and almost
9 every Vietnam veteran and veteran organization that there
10 is.

11 We also work very closely with 72 county veteran
12 service officers. This has made it a lot easier for us
13 to get information out to the veterans, because when the
14 veteran wants to file a claim he goes through his county
15 veteran service officer.

16 We set up the hotline a little less than a
17 year ago, and already we have had over 4000 telephone
18 calls. I have not personally answered that many phone
19 calls, but I think that the calls coming in have given us
20 a good idea as to what the veterans of Wisconsin would like
21 to see, as far as programs for them and their families.

22 The joint finance committee has allocated
23 \$66,400 to the program, to be carried forward for another
24 year. What we would like to do in this coming year has
25 three parts:

1 We would like (1) to continue information and
2 our education coordination and promotion; (2) we would
3 like to have an extended outreach program, where we would
4 like to get more of the veterans into the VA hospitals to
5 be examined. We would also like to see their children be
6 examined.

7 As we had mentioned, only 4-5 percent of the
8 veterans from Wisconsin have gone to the VA for an
9 examination. This is an extremely low number, considering
10 the fact that we have contacted this many people.

11 I have been informed by the Veterans Administra-
12 tion Hospital in Madison, Wisconsin, that approximately
13 50 percent of the veterans who call up and have an appoint-
14 ment to come in for an examination eventually do not show
15 up.

16 There must be a reason for this. I think the
17 reason is because a lot of the veterans have received
18 letters already from the hospitals telling them that there
19 is no association between the problems that they perceive
20 they have and with Agent Orange.

21 This is one of the reasons why we have decided
22 to produce a television show which will be aired throughout
23 the State of Wisconsin, and hopefully on PBS nationally,
24 which will give answers to the veteran as to what the
25 Veterans Administration is actually doing.

1 We hope that this will encourage the veteran
2 to come in and get the examination. We feel that, if they
3 are having problems, that those problems should be taken
4 care of, whether or not they are due to Agent Orange.

5 If they are having physical problems, they should
6 be treated.

7 Also, we have had a tremendous response from the
8 private physician community in the State. The Wisconsin
9 State Medical Journal recently printed an article called
10 "Agent Orange-The Physician's Dilemma."

11 The article listed a protocol for treatment or
12 examinations of Vietnam veterans, and we think this is
13 very helpful.

14 We have also been sending out examination proto-
15 cols to other physicians who request them. I think we have
16 had approximately 10 or 15 requests so far.

17 A lot of the Vietnam veterans from the State
18 have to travel long distances to get to the Veterans
19 Administration Hospitals--in some cases up to 300 miles.
20 This is very inconvenient for them, especially if they
21 don't receive any travel pay.

22 This is why we feel it is important that private
23 physicians get involved. It is also important because a
24 lot of physicians do not know too much about environmental
25 medicine.

1 Veterans have been going to their private
2 physicians for a long time and have been getting the
3 runaround, basically saying "We don't know what the problem
4 is--go to the VA."

5 So this is a great help, I think.

6 With increased awareness have come questions
7 concerning who is the greatest risk and what these risks
8 are.

9 Being informed of a potential hazard is insuf-
10 ficient. Studies in other States have suggested that
11 veterans reporting skin conditions have a higher incidence
12 of liver problems and birth defects among their children.

13 Rumors are many and facts are few. I believe
14 that the program which the State of Wisconsin has right
15 now, can begin to provide leads and some scientifically-
16 defensible analysis.

17 We will search for more funding to continue the
18 program, and this will be sought very rigorously. We
19 would like to see more funding, because we believe that
20 once initiative is lost, a big part of the program is lost.

21 So, we thank the committee here for the support
22 that we have gotten in our program when we have called up
23 and asked for materials or advice or information as to how
24 we can better deal with the veterans in Wisconsin, and
25 we would also like to thank other States who have also

1 given us advice and help in how to run our program.

2 Thank you very much.

3 DR. SHEPARD: Thank you. Are there any
4 questions from members of the committee?

5 QUESTION & ANSWER SESSION

6 DR. FITZGERALD: I just wanted to bring to your
7 attention the fact that you said there is a concern about
8 travel funds for the veterans to get to the VA Hospitals.

9 If they have a scheduled examination at the
10 Veterans Administration Hospital they are entitled to
11 travel funds. A drop-in, no; but a scheduled examination
12 entitles them to travel funds.

13 MR. LAURIN: Well, is that only if they file a
14 claim?

15 DR. FITZGERALD: It has nothing to do with a
16 claim. If they have a scheduled examination at a Veterans
17 Administration facility, they are entitled to travel funds.

18 DR. SHEPARD: They have to request it,
19 though; isn't that right, Dr. Fitzgerald?

20 DR. FITZGERALD: They have to request it, yes.
21 They cannot just be a drop-in.

22 DR. SHEPARD: But do they have to request
23 the reimbursement? It isn't automatic, in other words.

24 DR. FITZGERALD: That's right.

25 MR. LAURIN: Okay. I think that is where the

1 problem lies, in that the veterans don't request it. They
2 think that it is coming to them automatically.

3 DR. SHEPARD: So that would be something
4 you would have to sort out.

5 Dr. Moses?

6 DR. MOSES: I was curious about this county
7 veteran service officer role; is that peculiar to the
8 State of Wisconsin? Or is this something that all States
9 have? And is it a part of the Veterans Administration?

10 DR. SHEPARD: Many States have it.

11 DR. MOSES: Is it from the Veterans Administra-
12 tion? Or is this something from the State?

13 DR. SHEPARD: A State organization.

14 MR. LAURIN: A State organization; correct.

15 DR. MOSES: That sounds like a very good point
16 of contact and a good field way to work on services to
17 veterans.

18 MR. LAURIN: New York State has such a system.

19 DR. MOSES: Does New Jersey?

20 DR. KAHN: Yes, we do.

21 DR. MOSES: Are they involved in what you do?

22 DR. KAHN: Yes, they are intimately involved.

23 Our office is down the hall from the State
24 Office of Veterans Affairs.

25 DR. MOSES: Is that county veterans service

1 officer a veteran usually?

2 DR. FITZGERALD: He is usually a member of one
3 of the veterans organizations.

4 DR. SHEPARD: But he is paid by the State.

5 DR. FITZGERALD: He is paid by the State, yes.

6 DR. SHEPARD: Are there any other questions
7 by the members of the committee of our friends from
8 Wisconsin?

9 [No response]

10 DR. SHEPARD: Well, thank you very much,
11 gentlemen. I will look forward to your participation in
12 our meeting this afternoon.

13 Let me say again that this is the first of this
14 kind of information sharing that we have had, and I hope
15 that it is the first of many.

16 I want to reaffirm the position of our office
17 to act as a clearinghouse for the exchange of information,
18 advice, what have you. I am delighted that you have heard
19 from these two States, and I am sure that this will be
20 one of many forthcoming.

21 Let us now move on to the next item on our
22 agenda. Dr. Lingeman, would you please introduce Dr.
23 Cantor?

24 DR. LINGEMAN: I would like to first point out
25 that the title of the talk is somewhat misleading, in that

1 the Soft Tissue Sarcoma Report is not really what Dr.
2 Cantor is going to talk about.

3 And that is something that has been talked about
4 as a possible project involving a cooperate effort between
5 the AFIP as a source of location of soft-tissue tumors, and
6 a possibility of an epidemiological study rising out of
7 that.

8 But the NCI has been engaged in several other
9 types of studies which definitely have to do with the
10 carcinogenicity of herbicides.

11 Some are in the final stages, some are in the
12 planning stages; and therefore Dr. Cantor, of the
13 Environmental Epidemiology Branch of the National Cancer
14 Institute, is here to summarize the efforts of his
15 department with reference to the herbicides.

16 STUDIES OF THE ENVIRONMENTAL EPIDEMIOLOGY BRANCH-NCI

17 DR. CANTOR: Thank you very much for inviting me
18 here today, Dr. Shepard.

19 Actually the study that we are planning is one-
20 quarter of this presentation; so we will at least be talk-
21 ing about that a little bit.

22 The Environmental Epidemiology Branch at the
23 National Cancer Institute is involved in a wide range of
24 epidemiologic studies where cancer is either known or
25 suspected to be the end point of particular exposures.

1 In the area of herbicides we were led to this
2 area from three general concerns.

3 One is a general concern about pesticides of
4 all kinds and exposures that both the general population
5 and in particular farming populations have.

6 The second is a series of studies based on
7 mortality records. The first level of studies that was
8 generated by the system of county cancer-mortality records,
9 kept at the National Cancer Institute, in which correla-
10 tions first of all with leukemia and farming seemed to be
11 evident. The second are other studies where non-Hodgkins
12 lymphoma seems to be elevated among people in farming
13 areas.

14 The third general impetus for these studies
15 stems directly from the Swedish studies by Hardell, Erickson,
16 Axelson and other workers, which I'm sure most of you have
17 heard of, where they saw associations between both soft
18 tissue sarcomas, non-Hodgkins lymphoma, and I believe
19 Hodgkins Disease, and related that to exposure to chlorin-
20 ated phenoxy acidic acids.

21 I have brought along three viewgraphs today.

22 [Showing of viewgraph]

23 DR. CANTOR: This first one is a very general
24 description of the four studies I would like to discuss
25 with you.

NCI STUDIES INVOLVING POSSIBLE HERBICIDE EXPOSURES

<u>STUDY</u>	<u>INSTITUTE</u>	<u>DESIGN</u>	<u>SIZE</u>
AERIAL PESTICIDE APPLICATORS	NCI/FAA	COHORT MORTALITY RETROSPECTIVE FOLLOWUP	N = 10,000
SOFT-TISSUE SARCOMA (FEASIBILITY)	NCI/AFIP	CASE-CONTROL INTERVIEW	N = 100
PEST CONTROL OPERATORS	NCI	COHORT MORTALITY RETROSPECTIVE FOLLOWUP	N = 4,500 (2,000 LICENSED IN CATEGORIES WITH POSSIBLE HERBICIDE EXPOSURES)
LEUKEMIA/NON-HODGKIN'S LYMPHOMA	NCI/U.MN	CASE-CONTROL INTERVIEW	N = 300 LEUKEMIA N = 300 NHL

1 Since I do have particular viewgraphs on the
2 first two that are mentioned there, I'll just discuss
3 right now the third and the fourth.

4 Perhaps before going into that I will just
5 mention that here we see representatives of two general
6 types of study.

7 The first and third studies, that is, aerial
8 pesticide applicators and pest-control operators, are
9 studies in which the study group is based on exposure.

10 That is, aerial pesticide applicators have known
11 or suspected exposures to pesticides. Pest-control
12 operators also have exposures to pesticides of various
13 kinds.

14 Both studies share the characteristic that they
15 are retrospective follow-up studies in which mortality is
16 used as the end point. We do seek out death certificates
17 in these studies.

18 The second and fourth studies are both case-
19 control interview studies in which entry into the study
20 is based on diagnosis of a particular disease in an indi-
21 vidual.

22 Then we will go ahead and choose matched controls
23 and interview the controls in the same way, and then look
24 for differences between cases and controls in terms of
25 their exposure.

1 Now, going on to the third study, this is a
2 study which is near completion. The cohort is based on
3 pest control operator licensing records from the State
4 of Florida; and these were people who were first licensed
5 from the mid-40s to the late-60s.

6 We have almost completed follow-up on this group
7 of 4500 persons, of which about 2000 are licensed in
8 categories with possible herbicide exposures.

9 What that means is that every time Florida gives
10 a license to a pest-control operator they are licensed for
11 specific types of pesticide application. One of those
12 categories is weed-killers in lawn and weed control.

13 As I say, we should have results from that study
14 certainly by the end of this year, and probably in three
15 months, I believe.

16 The last study mentioned there is a little
17 misnomer. It should be leukemia and non-Hodgkins lymphoma.
18 The data collection is being done under contract to NCI
19 from the University of Minnesota. Drs. Lenos, Shumann, and
20 Gibson at the University of Minnesota are just/^{now}going out
21 in the field to do a case control interview study of
22 patients diagnosed with either of these two diseases,
23 either in the last year or for the next two years.

24 Based on previous records, we plan in that study to have
25 300 leukemia cases, 300 cases of non-Hodgkins lymphoma,

1 and matched controls.

2 Now, one of the primary purposes of that study
3 is to look in great detail at occupational exposures,
4 specifically farming exposures.

5 The questionnaire, which is now nearing its
6 final stages, goes into great detail in asking about parti-
7 cular crops that were grown and livestock that people kept
8 and particular herbicides, fungicides and insecticides
9 that were used. We ask it in a number of ways--by generic
10 name and by brand name. There is a tremendous complexity
11 of brand names that have been used in the past.

12 The study is being conducted of all cases identi-
13 fied in hospitals within Minnesota, ^{includes only} but / residents who
14 are living outside of the Minneapolis-St. Paul area. This
15 will increase the probability of getting the population
16 that is at least 25 to 30 percent farmers, at some point
17 in their lives.

18 Let's turn now to the next viewgraph.

19 [Change of viewgraphs]

20 DR. CANTOR: This goes into some detail on the
21 study of aerial pesticide applicators.

22 This is a study that we are doing in conjunction
23 with the Federal Aviation/^{Administration} The FAA requires of
24 all commercial pilots that they take a medical exam, at
25 least for Second Class Pilots, once a year.

AERIAL PESTICIDE APPLICATORS (NCI, FAA)

- RETROSPECTIVE MORTALITY STUDY
- COHORT SIZE 10,000
- FAA MEDICAL EXAM FILE, 1965 - 1979
- 2 COMPARISON GROUPS
 - FLIGHT INSTRUCTORS (FROM FAA RECORDS)
 - U.S. GENERAL POPULATION
- FOLLOWUP IN PROGRESS
 - FAA RECORDS
 - SOCIAL SECURITY ADMINISTRATION
 - MOTOR VEHICLE BUREAU
 - TELEPHONE DIRECTORIES
 - OTHER
- EXPOSURE INFORMATION IS LIMITED
 - INFERRED FROM RESIDENCE
 - EMPLOYERS (??)

1 At this medical exam the pilot reports his
2 primary type of commercial aviation activity. One of the
3 10 categories that they use is pesticide applicator.

4 We have identified approximately 10,000 indivi-
5 duals who, at least once between 1965 and
6 1969 said that they were
7 aerial pesticide applicators. Most of these people, in
8 medical
fact, at their yearly/exam, reported this year after year.

9 We will be following up this group through the
10 FAA records themselves, Social Security Administration
11 records, Motor Vehicle
12 with
Bureaus and telephone directories and also / other
13 including
resources, perhaps/voter registration records, to establish
14 the of all individuals
vital status/as of a closing which is now tenta-
15 tively set as mid-1979.

16 Through Social Security we have already identi-
17 fied 550 deaths within this group
18 of 10,000; and my suspicion is that there are at least
19 200 or 300 more that will be uncovered.

20 In this study we will be using two comparison
21 groups.

22 should be chosen so as
The comparison group/to be as much like
23 the study group as possible.

24 were used for comparison
If only the U.S. general population,/it
25 could be argued that there is something different about

1 people who fly planes, either in terms of their
2 general health, socio-economic status or area of the
3 country.

4 To address this issue, we have selected a matched
5 control group of 10,000 flight instructors from FAA records. .

6
7 They are matched on age and
8 area of the country.

9
10 One of the problems in this study
11 will be the kind of exposure information which
12 is available.

13
14 We will first analyze
15 this group by area of the country, to see if there are / any unusual patterns
16 of mortality by region.

17 Secondly, we will go to employer
18 records.

19 If there is anything unusual
20 going on in the population at large or in any
21 particular regional groups, we will seek this addi-
22 tional information. But I think we have to recognize at
23 the outset that / characterization of exposure will be a major problem.

24 The next viewgraph, please.

25 [Change of viewgraphs]

SOFT TISSUE SARCOMA (NCI, AFIP)

- **CASE-CONTROL DESIGN**
- **CASES FROM RECENT AFIP ACCESSIONS**
- **DESIGN AND FEASIBILITY PHASE**
 - **QUESTIONNAIRE DESIGN**
 - **TELEPHONE INTERVIEW OF 100 CASES OR NEXT OF KIN RESIDING IN "HIGH EXPOSURE" AREAS**
- **QUESTIONNAIRE DESIGN**
 - **DEMOGRAPHIC BACKGROUND DATA**
 - **OCCUPATIONAL HISTORY**
- **PLANS FOR SELECTION OF ADDITIONAL CASES AND OF CONTROLS WILL FOLLOW FEASIBILITY PHASE**

1 DR. CANTOR: This viewgraph describes in brief
2 the study that Dr. Lingeman referred to, which is
3 presently in the feasibility phase.

4 Eventually we will have a case control study
5 underway, and the cases will be identified from recent
6 accessions of the Armed Forces Institute of Pathology.

7 Soft tissue sarcoma presents
8 tremendous diagnostic problems, and for that reason a
9 fair percentage of all of the soft tissue sarcoma diag-
10 noses or potential diagnoses in the United States wind up
11 at AFIP. So at least we have the possibility of getting
12 about 30 percent of the cases?

13
14
15
16 In the feasibility phase, we will
17 select 100 cases--100 male cases--that have been
18 identified by AFIP from areas which
19 are identified as high-exposure areas.

20 What we mean by high-exposure areas would be
21 areas where herbicides have been
22 in quality, such as and
23 used/ wheat-growing areas,/rice and forestry areas.

24 At the moment we are looking into various ways
25 of accessing the AFIP files, and we are in the discussion

1 phases of developing a telephone questionnaire which will
2 obtain demographic data for these indivi-
3 duals/ and as detailed an occupational history as can be
4 obtained with a telephone interview.

5 This will, of course, include a history of
6 military service.

7 After the feasibility phase we will develop
8 plans for selection of additional cases and of controls.

9 That's all for my formal presentation. I will
10 be happy to entertain any
11 questions that you might have.

12 DR. SHEPARD: Surely; and thank you, Dr.
13 Cantor.

14 Does any member of the committee have questions
15 of Dr. Cantor?

16 QUESTION & ANSWER SESSION

17 MR. SULLIVAN: I have one. Would mind saying
18 why you picked the sample size of only 100 for the last
19 study?

20 DR. CANTOR: That's a feasibility phase of the
21 study; that is not the final study design.

22 What feasibility means is that accessing cases
23 through AFIP presents certain difficulties that should
24 be recognized.

25 First of all, when AFIP obtains information

1 about a person they get it directly from the pathologist
2 and not the primary-case physician. So getting back to
3 a case or the next-of-kin, if the person is deceased,
4 will involve first going to the pathologist, then to
5 the primary-care physician before we reach the patient.

6 We have a little bit of experience with this in
7 one or two other studies, but we feel we need more before
8 deciding^{on}/the final design of this particular study.

9 In our judgement 100 cases will be quite ade-
10 quate to give us enough experience to be able to deal with
11 that question.

12 MR. SULLIVAN: What kind of confidence level do
13 you expect to draw from only 100 cases?

14 DR. CANTOR: None at all.
15 I repeat
16 This is a feasibility phase of a study

17 The detailed study design will not be in
18 existence

19 until after we have finished this phase.

20 MR. SULLIVAN: Thank you.

21 DR. SHEPARD: Dr. Suskind?

22 DR. SUSKIND: The AFIP has been collecting
23 biopsies and autopsy material of Vietnam veterans who have
24 had cancer, I do believe. Is that not so?

25 DR. SHEPARD: Yes. But not exclusively.
We are establishing an AFIP registry of any Vietnam

1 veteran. Yes, there are some cancers among them.

2 DR. SUSKIND: Would any of the soft tissue
3 sarcomas of the feasibility study come from that group?
4 Or is it likely that some of them might come from that
5 group?

6 DR. CANTOR: I will have to turn to Dr. Lingeman
7 to help me on that.

8 DR. LINGEMAN: These are the cases which would
9 be accessioned routinely to the AFIP / registry from the
10 Registry of Environmental Pathology. These / would be
accessioned by the AFIP and referred to the
11 Registry of Soft Tissue Pathology. All
of soft tissues,
12 diseases / not just sarcomas are accessioned and examined by pathologists
who specialize in these diseases. We obtained a computer
13 writeout listing every case of soft tissue sarcoma
accessioned
14 that was/in the AFIP in the last five years in the
15 Registry of Soft Tissue diseases.

16 Now it may turn out that some of these
17 cases are also in the Agent Orange Pathology study.

18

19

20 DR. SHEPARD: Any other questions from
21 members of the committee?

22 [No response]

23 DR. SHEPARD: Well, thank you very much
24 Dr. Cantor. We certainly appreciate your sharing that with
25 us, and I hope we can look forward to a further update on

these
1 / efforts.

2 RECESS

3 DR. SHEPARD: We are running a little
4 ahead of schedule. Let's take about a four-minute break.

5 [Whereupon, at 10:50 a.m., the meeting was
6 recessed.]

7 AFTER RECESS

8 [11:00 a.m.]

9 OPEN DISCUSSION - FUTURE EDUCATIONAL EFFORTS

10 DR. SHEPARD: In the announcement letter
11 for this meeting the members of the committee
12 were asked to come to this meeting prepared to advise us--
13 this is an advisory committee--to advise the VA on ways
14 in which we could improve the process of educating our
15 medical staff and other health care providers on the whole
16 issue of Agent Orange and related matters.

17 I would like now to have a rather open discus-
18 sion in the committee. If any of the committee members
19 have prepared such recommendations we would like to hear
20 from them now. If any of them have taken the time to
21 write them down, we certainly want to incorporate them in
22 the proceedings of the meeting.

23 So I will now open it up to general discus-
24 sion on ways in which the VA can improve its educational
25 process for physicians and other health care providers.

1 As you know, we have provided a 30-minute
2 video tape that was designed for the purpose of hoping to
3 educate concerned veterans.

4 Now we need to get perhaps more scientific
5 information together; so I will just open it up for
6 discussion.

7 Does anybody have any suggestions?

8 DR. KEARNEY: Barclay, this may come as a little
9 different approach to the thing; but in agriculture we
10 are concerned about technology transfer of, say, research
11 to the farming community.

12 Over the last 30 to 40 years we have been
13 extremely successful working with our extension service
14 and ID information people.

15 It is a very good success story of translating
16 information to our county agents at the county level to
17 work with the farm community.

18 I am suggesting that we have some techniques
19 and equipment and approaches that might be helpful to
20 you.

21 As a third party, which does not understand the
22 what
difficult subjects like/we are dealing with on a medical
23 basis, you might want to chat with them as to how they
24 would handle such a situation; because they come at it
25 not understanding all of the great technology and medical

1 terminology, but they would come at it as a third party
2 who has had a lot of information-exchange experience,
3 transfer of technology, taking a complex message and
4 making it fairly simple, and a good web of distribution.

5 So we would make available to you these people
6 we have who are illustrators, broadcasters, information
7 specialists, who might be of some assistance to you--that
8 is, as a third party looking at a difficult subject and
9 making it somewhat understandable and responsive.

10 DR. SHEPARD: Thank you very much, Dr.
11 Kearney. That is very kind of you.

12 That is something that we need to always
13 remember, that not only^{is} the factual information important
14 but also the way it is presented.

15 You can have a very good idea , but if it is
16 not presented in such a way that it is readily understood
17 then it is of little use.

18 Yes, Dr. FitzGerald?

19 DR. FITZGERALD: You mentioned the difficulty
20 of keeping the environmental physicians aware of the
21 desirability of certain examinations and facts concerning
22 Agent Orange.

23 You also have a changing population in these
24 physicians who are examining. Might it not be helpful to
25 utilize the hospitals in close geographic proximity to the

1 area that might be of concern?

2 You might have these environmental physicians,
3 newly appointed or the ones who might not be doing as good
4 a job as some of the others, to visit a hospital where
5 you think the job is being done well.

6 We had criticism, for instance, of East
7 Orange. It might be applicable there, because certainly
8 the information that we are getting at the present time
9 is that the examinations are being accomplished within a
10 reasonable period of time.

11 Most of the information that we are getting is
12 that they are being scheduled within three weeks. The
13 longest is usually five weeks, but most of them are within
14 two to three weeks.

15 DR. SHEPARD: I'm glad to hear you say that
16 because that has been our hope.

17 Of course we have embarked on a number of
18 initiatives. We have now set up a conference call system
19 on an every-other-month basis.

20 If we have something urgent that needs to get
21 out, as I indicated on this matter of setting the record
22 straight on Agent Orange exams versus claims, we have
23 already scheduled for Dr. Turner Camp's weekly conference
24 call, the conference call for administrative services, and
25 our own conference call.

1 We also have our Agent Orange newsletter, which
2 will soon be coming out in the next edition. So we
3 have a number of opportunities.

4 But I am concerned more specifically at this
5 time -- I don't want to exclude any discussion, but what
6 I am particularly interested in is putting together an
7 educational package that will best serve the needs of our
8 environmental physicians.

9 Of course, another thing is that we are trying
10 to make the dioxin conference, and this is one reason why
11 I have been so interested in it, this fall, another
12 educational symposium for our environmental physicians,
13 similar to and perhaps more scientifically oriented than
14 the one we had last May.

15 DR. FITZGERALD: We also received some criti-
16 cism of East Orange as far as that dermatology examination
17 is concerned, and we are in the process of trying to get
18 information about that.

19 DR. SHEPARD: Does anybody else have any
20 suggestions? Dr. Suskind?

21 DR. SUSKIND: I have some questions about the
22 differences between the circular which expired on April
23 the 16th, which concerns the examination of veterans who
24 have been exposed to Agent Orange, or who believe they
25 have, as compared to the new one.

1 Since we just got this new one in today's folder,
2 I wonder if you would be able to tell us what the dif-
3 ferences are, if any?

4 DR. SHEPARD: The differences are not
5 substantial. The previous circular had some ambiguities
6 in it, and the code sheet--the encoding document--which
7 was used for purposes of entering the data that evolved
8 from the examination or laboratory studies into the com-
9 puter data bank is now in a more readable printed form
10 and hopefully will obviate some of the errors that have
11 been made in that process.

12 But there are essentially no major substantive
13 changes between the two circulars.

14 DR. SUSKIND: To follow up on this, what is
15 being done to train the physicians who are likely to do
16 this examination, properly?

17 I believe there were two or three workshops,
18 training programs, in the last couple of years. I remember
19 the first one.

20 Are there any plans to have periodic training
21 sessions for the examining physicians?

22 DR. SHEPARD: I gather what you mean is
23 in terms of actually the conduct of the examination itself.

24 DR. SUSKIND: Well, I think that, while forms
25 are useful in that they highlight the questions that need

1 to be asked, whether by discussion or by physical examin-
2 ation or by laboratory examination, the most important
3 aspect of this is how well-trained is the individual to
4 do this?

5 DR. SHEPARD: That's a good point, and I
6 guess that's part of the reason this time has been allotted
7 to our deliberations.

8 If you have some specific suggestions we would
9 very much appreciate them.

10 To answer your question have we conducted any
11 training programs, other than the two educational confer-
12 ences we have had no formal training programs.

13 DR. SUSKIND: Has there been any attempt, for
14 example, to assign teams of physicians at installations
15 specifically for the examination of Vietnam veterans?

16 This would probably get rid of the possibility
17 of anybody doing it--that is any VA medical officer
18 doing the examination--but rather people who are trained
19 to do the examination, and who know what they are looking
20 for.

21 DR. SHEPARD: Let me make sure I understand
22 your question. No, there have not been any formal efforts
23 at training teams of physicians in VA hospitals.

24 We have identified, in each of our medical
25 facilities, an environmental physician with whom we

1 hopefully maintain an ongoing dialogue.

2 We provide him with what information we have;
3 they call my office--I must take four or five calls a day
4 from environmental physicians--with a variety of questions.

5 In terms of specific instructions on how to con-
6 duct an examination for Agent Orange, we have not done
7 that. But if you have some suggestions along those lines,
8 we sure would like them.

9 DR. SUSKIND: In order for this epidemiological
10 study to be successful, you are going to have to do just
11 that.

12 I am saying that if it is important for a well-
13 conducted clinical epidemiological study to have trained
14 people with a manual of examination, then it is equally
15 important at each of the VA hospitals doing the routine
16 examinations to have the same kind of training; perhaps
17 not a manual as will be eventually developed for the
18 clinical epidemiology examination, but --

19 Otherwise, the examinations are going to con-
20 tinue to be catch as catch can examinations. That's why
21 we are hearing from hospitals, such as the one in East
22 Orange, that the veterans are not getting proper atten-
23 tion.

24 DR. FITZGERALD: I think I can clarify that a
25 little. It is my understanding, Dr. Suskind, that the

1 designated environmental physician is doing the Agent
2 Orange examinations. Now, is this not so?

3 DR. SHEPARD: In the majority of cases I think
4 that the examination is, for the most part, being con-
5 ducted by the environmental physician.

6 I know that in some cases environmental physi-
7 cians supervise other physicians.

8 The State of Minnesota conducted a very vigor-
9 ous and very successful outreach program.

10 They mobilized their county officers, they
11 identified the Vietnam veterans, they encouraged Vietnam
12 veterans to present themselves to the Minneapolis VA
13 Hospital, and that hospital was suddenly inundated with
14 a large number of requests for Agent Orange examinations.

15 Much to their credit, they took on this enor-
16 mous workload with considerable expertise, and they
17 conducted over 1000 examinations in a very short period of
18 time.

19 It would obviously be impossible for one
20 physician to do all of that; so that's perhaps an extreme
21 case.

22 But Dr. Petzel, who is the Chief of Staff of that
23 hospital, organized a system in which he set up teams to
24 conduct these examinations.

25 It is difficult to generalize, because different

1 circumstances exist in different parts of the country; so
2 I think in the past we have done things on a case-by-case
3 basis, if you will, depending on the needs at a given
4 location.

5 I certainly agree with you that it would be
6 ideal if we could have environmentally trained or
7 physicians trained in the particular needs of environmental
8 problems.

9 Unfortunately, the VA has not been structured
10 over the years in this area. Consequently, as I have
11 said so often, when the Agent Orange problem hit us we
12 didn't have, and still to a large extent don't have, the
13 particular expertise to deal with this.

14 The purpose of the registry, first and foremost,
15 was to identify Vietnam veterans concerned about possible
16 health effects, to get some rough idea as to the current
17 state of their health, and to document this, and to enter
18 them into the registry so that in such time as the more
19 elaborate and more sophisticated research efforts started
20 to produce data, we would have the opportunity and the
21 capability of reaching these veterans.

22 But certainly your point is well taken, and if
23 we had the resources we would --

24 I would like to remind the group that all of this
25 registry has been done essentially without any additional

1 resources being devoted to it; so there are great
2 expectations, and obviously we would like very much to do
3 a lot more than we have done to date.

4 I am not begging the question; I wish and I hope
5 that we will, over the years or the months to come, put
6 more and more of this kind of expertise into the field.

7 But, again, if you have specific suggestions
8 about how we could affect such an effort, we would very
9 much welcome them. We really need that advice from you

10 so that we can present it to the new Administra-
11 tor or the Congress or the President himself, if need be.
12 If additional resources are required to affect a more
13 productive program, then we can highlight those.

14 Yes, Dr. Moses.

15 DR. MOSES: You know, for quite a bit of time I
16 have felt about this whole Agent Orange situation, in terms
17 of the veterans, that we are suffering from what I call
18 "the myth of the experts,"

19 Most doctors that I know are fairly intelligent
20 people, and they know how to do a physical examination.

21 It seems to me that what is needed at the first
22 point is a very traditional, ordinary kind of physical
23 examination.

24 Veterans used to call me and say, "I want that
25 Agent Orange test," or, "I want that dioxin test," or

1 they tell me, "You are the only one that knows how to do
2 this test," in this area, or whatever.

3 I think that really isn't the case with the
4 greater percentage. It seems to me that there ought to
5 be--and I have discussed this with other people here in
6 this room--that there could be some initial level at which
7 we know all doctors function quite adequately, and I know
8 that the VA doctors can function quite adequately in this.

9 So this fulfills the veterans need who comes in
10 and says, "I have a problem." There are very traditional
11 ways to assess whether there is a problem, what is their
12 past medical history--all the information here can be
13 incorporated as an adjunct to the past medical history.

14 Then it seems to me there has to be a next step
15 for certain veterans who will fall out from that, who have
16 additional problems, who may have specific problems of
17 interest.

18 I think there are two areas that have been
19 brought up ad nauseum which is the same thing that I see
20 in the veterans that I see: skin problems and worry about
21 problems with their children, either children they already
22 have who have learning problems or who are hyperactive.

23 Very rarely is it actual birth defects them-
24 selves. It is usually a behavioral or an activity-type
25 of problem. I don't know if this has been the experience

1 with other people or not.

2 It seems to me, if the VA really wants to do
3 this it can help itself a lot by letting the traditional
4 doctors do the traditional things and save the experts
5 and the people that they train--and I have an idea of how
6 you might do that, too--to train those people to deal with
7 what falls out from that initial examination.

8 It is not really a screening. I think this was
9 a big mistake in the beginning--people thought they were
10 being screened. I think they need a very detailed medical
11 examination which the VA is quite able to do.

12 Now, in terms of skin--and, Dr. Suskind, one of
13 the people on this committee, is quite able to help with
14 this--I think a good slide show on chloracne, showing what
15 it looks like in the acute, a severe situation, can be
16 used.

17 We have some and I'm sure Dr. Suskind does, Dr.
18 Taylor, Dr. Carter--there are lots of people who have some
19 of this--for the physician showing what chloracne is,
20 with some expert commentary from someone like Dr. Suskind,
21 to answer some of the other questions.

22 That could help a lot with people who are seeing
23 something that couldn't remotely be that, but who have no
24 idea what it is. I think that could be done very easily.

25 I think the other area where a slide show should

1 be used, but I don't know who the experts in this area
2 are, I think someone should attempt to deal with this whole
3 genetic question and prepare a slide show on that.

4 There is nothing wrong with saying, "We don't
5 know." I don't see anything wrong with that.

6 I think that could take care of those two
7 problems. You could put those things together, duplicate
8 them, ship them out.

9 EPA has done this very successfully with pesti-
10 cides, training people in the migrant health clinics
11 regarding toxic exposure to pesticides, and what physicians
12 should do, and how to treat, and that sort of thing.

13 I don't know if this is within something the
14 VA could do, but I think it is a very simple thing, would
15 not cost very much money, and I think it could really
16 help.

17 DR. FITZGERALD: I agree with Dr. Moses, but
18 there is one factor in this that I think is essential; and
19 that is to have this designated physician doing these
20 examinations not because of his expertise, per se, but
21 because of his sympathetic approach to the individual.

22 All too frequently a physician who does not have
23 this interest at heart will feel provoked at having to do
24 such an examination. That is why I think it is essential
25 that an individual who is anticipating doing this type of

1 examination and who will be sympathetic to the veteran is
2 a major portion of this.

3 Then I agree with you, if he finds anything,
4 to refer to an expert in the field.

5 DR. SHEPARD: Dr. Hodder?

6 DR. HODDER: There is one point I would like to
7 make. People look at the epidemiologist as someone who
8 goes out and gets data; but we have also learned some
9 other things along the road in terms of how getting data
10 can be a problem.

11 You mentioned that this isn't really screening,
12 but in some respects certainly it is a screening program.
13 One of the great dangers you can get into in a screening
14 program is looking for too much.

15 What I am particularly interested in concerning
16 that is, when you look for a screening test, you want a
17 definite series of steps that you are going to make after
18 that to be laid out.

19 That allows you to do a cross-benefit analysis
20 of, "I'm looking for a possible condition; I have to do
21 this type of diagnostic test and perhaps this type of
22 intervention," which also entails a certain amount of risk.
23 So we have a cross-benefit type of thing.

24 We could certainly find pancreatic cancer, for
25 example, using a cat scan; but with the false positive and

1 requiring abdominal surgery to rule that out we would
2 probably cause more damage than good.

3 I am concerned about
4 the educational component here when
5 you develop such a large battery of tests, /you are going
6 to get an awful lot of false positives in this.

7 Therefore, I think one of the guidelines that also needs
8 to go out is what one does if one gets a mild elevation
9 of billirubin, say or a mild elevation of
10 alk phos / otherwise in fact, the screening program potentially
11 could do some harm that was not intended.

12 DR. MOSES: Could I respond?

13 DR. SHEPARD: Sure.

14 DR. MOSES: I feel very strongly about this,
15 and I am going to speak very strongly about it.

16 I think we have to separate epidemiology and
17 service. These veterans are not coming to be part of the
18 study. They are coming because they want to know, "Doc,
19 what's wrong with me?" And, "Can it be treated--whatever
20 it is?"

21 I think that there is a lot of confusion on this
22 score, and I think that is a lot of the problem with
23 doing what really needs to be done.

24 Many of the veterans now know that there are
25 not definitive answers to a lot of these things, and I

1 have found veterans very acceptable to the concept, "Well,
2 let's just find out what's wrong. Let's see if you are
3 okay. We'll check everything."

4 And then I say, "We may not know if this is from
5 Agent Orange or whatever exposure, and if there is anything
6 wrong we will follow it up."

7 That is why we don't take anybody in our clinic
8 unless we know that we are going to be able to follow
9 these things up, and we make a commitment to follow these
10 things up.

11 Now that is very different than sending out a
12 big circular, getting all of the veterans to come in to
13 do an epidemiological study; although I agree with Dr.
14 Suskind, very much so, that whoever is doing either one
15 of these things should be knowledgeable.

16 But I feel that we are going to be doing a
17 disservice to veterans if we bring them in for examina-
18 tions under the term "service," and try to use that
19 information as an epidemiological survey, when that well
20 might be self-selective, they are coming in for all kinds
21 of reasons.

22 I think that is one of the problems that we get
23 into, that we want to give service and say, "Well, as long
24 as all of these people are coming in anyway, let's get
25 this information and get that information."

1 I frankly don't think that that's an epidemiolo-
2 gical survey. We have talked about this, Barclay, several
3 times.

4 I think what has to happen is we have to give
5 service to these veterans, as well. To me, that's still
6 what is missing. I am still getting calls from veterans
7 all over the country.

8 We should give them service if the VA is doing
9 its job. When the veteran is going there and getting the
10 service, really all they want to know is about them,
11 personally.

12 I think that is do-able, I really think that is
13 do-able, and I think it is a very different question than
14 trying to answer the epidemiological question of liver
15 disease, of skin problems, cancer, and birth defects. I
16 think that is a different question.

17 DR. HODDER: I think we are talking on two
18 different points here, actually.

19 The point I am concerned about is, if you take
20 apparently healthy 40,000 people and do an SMA-12 on them,
21 that
22 screening are the positives you are going to get out of that
23 predominately false positives rather than
24 true disease.

25 What I am concerned about is that a physician
used to health care, rather than in a context of looking

1 must
2 at healthy people, / be aware that there is a different
3 pattern of follow-up to a positive alk phos, for example,
4 in the healthy population than it would be in someone
5 who comes in complaining of being ill.

6 That is what I am concerned about. I think there
7 is an educational component that ought to go out, so that
8 the / ^{physicians} don't find themselves doing a more extensive battery
9 of tests than they ought to be doing.

10 DR. MOSES: Well, that is what this second level
11 thing that I suggested is.

12 For instance, one decides at what level of alk
13 phos you are going to trigger this second exam, or what-
14 ever. And that could be done by the initial examining
15 physician; say they know that this person has a heavy
16 alcohol intake, it well might explain it all, and they
17 may not even want to proceed any further.

18 That is going to give back to the primary
19 physician -- there are going to have to be these kinds
20 of decisions made all across the line or, I agree with
21 you, you are going to be overloaded with data and you are
22 really not going to know what it means.

23 But I still think that particular individual
24 really doesn't care about somebody else's alk phos. They
25 care about their own. And I think that's where the VA
26 is missing the boat.

1 I really think the VA is missing the boat on
2 this. It is not because they don't care.

3 We heard it today, and I think we heard it
4 very strongly. I don't know how pervasive a problem that
5 is, but if it is, I think we should try to address that
6 and not our epidemiological concerns as scientists. We
7 must address that also, but I think that is being addressed.

8 I think this other thing isn't being addressed,
9 and, even though it is problematic, if you do the tests --
10 that's the thing about doing tests on people: you are
11 stuck with trying to figure out what it means if you get
12 a positive result.

13 DR. HODDER: But what I am saying is/ ^{that for} a doctor
14 ^{an ill} who is used to doing a battery of tests on / population,

15 ^{the cost-benefit}
16 component ^{favours} doing ^{an invasive test}
17 ^{even} because his yield is very high/ on a population that is
18 walking around.

19 So what I am talking about is, the training of a
20 general internist. ^{For example, the}
21 hypertension workups years ago were developed in the
22 ^{such people as} tertiary centers by/ John Laragh and people at/ ^{Columbia P&S.} The
23 general physician started to use that workup, and they
24 were doing IVPs on just about everyone, the incidence of
25 dye actions and other problems from the testing

1 procedure was worse than what you would have had if you
2 hadn't bothered doing it.

3 DR. MOSES: Do you think there is anything
4 in this protocol like that? I didn't see anything.

5 DR. HODDER: Not if there is guidance; but if
6 you are doing an SMA-6 and an SMA-12, for example, on a
7 lot of those tests 5 percent of your population is going
8 to be read as abnormal.

9 So if you take 20 tests times .05 for each one,
10 you are going to have an abnormal test on probably 20 or
11 30 percent of your people.

12 Now what I am saying is in that case you need
13 guidelines to tell people not to jump on a test just because
14 they get one thing a little high. Repeat it in a certain
15 period of time or match it up with ^{other data} /-- you know, if he has
16 ^{SGOT elevation} a little / , but everything else is absolutely normal and
17 he doesn't have any liver tenderness or anything, ignore
18 it.

19 That is what I am saying. I think there is an
20 educational component here which is independent of Agent
21 Orange which may be very important to prevent an inadver-
22 tent problem--over-workup.

23 DR. SHEPARD: I think that is a good point.

24 DR. LINGEMAN--you had your hand up a minute ago?

25 DR. LINGEMAN: I think it's very nice that we

1 have so many other sectors involved in this--the State
2 Health Departments, and so forth--and I think they should
3 be commended.

4 I think each one of these can take a different
5 aspect and study one problem intensively, and yet not
6 dilute the effort.

7 If we study 100,000 veterans we may
8 be diluting the quality of the care and the
9 examinations.

10 We need to use more of the private sector, I
11 think. And I would like to see more of the private
12 physicians instructed on what the issues are.

13 Most people who are working already have some
14 sort of health insurance, so why tax the already over-
15 taxed VA system when we do have other possibilities?

16 People sometimes live great distances from
17 VA hospitals and would rather use their local physician
18 and their own health insurance to do this, and they may
19 get a better examination.

20 I mean that they will get more of this personal
21 attention you are talking about with someone who will sit
22 down with them and relieve their anxieties. I think we
23 are creating psychiatric problems in some of these cases.

24 DR. FITZGERALD: Unfortunately, Dr. Lingeman,
25 the statistics in 1979 showed that of the veteran

1 population who were hospitalized or were under care of
2 the Veterans Administration, the non-service connected
3 veteran, only 49 percent had outside health care insur-
4 ance.

5 DR. LINGEMAN: Well, we still need to do some
6 education, both of the VA physician and the non-VA physi-
7 cians. I think we could use the medical channels such as
8 the AMA, and I think the AMA convention should have a big
9 exhibit the next time they meet, in Las Vegas or wherever.

10 [Laughter]

11 DR. MOSES : Maybe they should meet in Orange
12 County.

13 DR. LINGEMAN: But the local medical societies could also be
14 brought into this with various educational programs.
15 Specialty organizations, such as the International Academy
16 of Pathology, for example, of which I am a member and
17 which has a committee that sponsors our registry, is a
18 good place to educate the pathologists on what is Agent
19 Orange? What is chloracne?

20 The average pathologist cannot look at a slide
21 and say it's acne, let alone it's chloracne.

22 We wanted to prepare an educational kit, and
23 we had to go to Japan to get a case of chloracne.

24 DR. SUSKIND: Well, I think that it would appear
25 that those who are looking for things like chloracne, and

1 have to go to Japan to find them, don't know what is
2 happening in the United States.

3 DR. LINGEMAN: I called Dr. Taylor and asked
4 him if he knew where I could get some biopsy material
5 from chloracne, and he was not able to furnish it.

6 lesions suspected of being chloracne
7 You don't biopsy, /ordinarily, do you?

8 DR. SUSKIND: Yes, we do biopsy. When we did
9 our study in Nitro we biopsied a lot of cases.

10 DR. LINGEMAN: May I ask you where those tissues
11 are now?

12 DR. SUSKIND: They are in my office.

13 DR. LINGEMAN: Would it be possible to get some
14 just to prepare educational material for pathologists?

15 DR. SUSKIND: Very easy to do that; sure.

16 I am a little concerned that we are off the
17 subject. I really am. I think what we really need to do
18 is to train the doctor, not just in the physical examina-
19 tion.

20 I agree with Dr. Moses that a screening examin-
21 ation can be a thorough routine physical examination; but
22 what kind of history is necessary? The history is not
23 an ordinary history. The history is not just a good
24 medical history but a focus history--you are looking for
25 something. And you are looking for a lot of things; so
that your history has to be keyed to the problem, just

1 like you do in cardiovascular examinations or pulmonary
2 examinations.

3 The historical information is a critical part
4 of this assessment. So the physician should, indeed, know
5 something about why he is asking these questions. And
6 that requires education.

7 You simply can't throw this in the lap of a
8 doctor and say, "Do it," because it isn't going to work
9 out. You have to educate him; you have to train him; and
10 you have to give him reasons why he or she is doing it.

11 Frankly, it is not necessary to train the VA
12 general physician or internist to be a dermatologist. It
13 isn't necessary to do that.

14 It is necessary, and we have had conferences
15 with the VA Dermatology Advisory Committee, which is a
16 very good one, on even training dermatologists as to what
17 chloracne is.

18 I have to tell you that the head of that commit-
19 tee came to the conclusion that there is no difference
20 between chloracne and acne vulgaris. He couldn't see the
21 subtle differences.

22 DR. KINNARD: Chuck, I would just like to under-
23 score what Dr. Shepard said earlier concerning what the
24 VA has actively done in terms of training their environ-
25 mental physicians.

1 Now, I wasn't involved in this activity when
2 the environmental physicians were selected, so I don't
3 know what the basis for that selection was.

4
5 I do know that last May at the Sheraton in Silver
6 Spring there was an Agent Orange conference in which each
7 one of the environmental physicians at the ^{VA}/medical centers
8 were invited, and most of them attended.

9 This ^{conference}/was designed to update knowledge on
10 what we had found out ^{about Agent Orange}/since the previous conference
11 was held.

12 I recall one of the hallmarks of that conference
13 was that there was a film shown which depicted the way
14 that a person presenting themselves at a VA medical center
15 with complaints about Agent Orange, how they should be
16 handled from the standpoint of the psychological input
17 as well as the actual examination by the environmental physicians.

18 The film that showed how it should be
19 done and how it should not be done. Now, I don't know
20 whether there was supposed to be any follow-up from that.
21 I think the REMC in St. Louis made that film.

22 Yes, there has been a considerable amount of effort
23 going into the training of the environmental physicians
24 to respond to both emotional concerns as well
25 as the actual medical concerns of these veterans.

1 MR. MULLEN: Dr. Shepard?

2 DR. SHEPARD: Yes.

3 MR. MULLEN: Getting back to last May at the
4 Sheraton, when you selected these environmental physicians
5 and appointed them, I specifically recall a lot of them
6 in the audience being hostile to that appointment.

7 In fact some of them even voiced the opinion
8 that the whole Agent Orange situation is political, that
9 it is not medical and shouldn't be taken care of in the
10 hospital.

11 Some of this hostility is reflected in the
12 complaints that are being rendered by the people who are
13 being examined. I think that is one of the biggest prob-
14 lems.

15 DR. SHEPARD: I certainly accept that to
16 a certain extent. I think it is also safe to say that
17 we often hear from the vocal minority. I would hate to
18 have it characterized, or I will not allow to go unchal-
19 lenged the impression that the majority of our environmen-
20 tal physicians don't care about the program or don't
21 think it is a medical issue.

22 That certainly has not been my experience, and
23 I have talked to a great many of them.

24 As I said, no additional resources were
25 placed in our medical facilities; so the whole Agent

1 Orange program has been conducted with existing resources,
2 both personnel and dollars.

3 So the task of carrying out this program has
4 to been in addition /their regular duties. That's one of the
5 problems, I'm sure. There are many problems.

6 But my experience has been that our environmen-
7 tal physicians, as a group, are doing extraordinarily
8 well. I think they have been very responsive to sug-
9 gestions that we have made.

10 As I say, I get calls very frequently, albeit
11 I may get a self-selected group of environmental physicians
12 but I am continuing this.

13 I will give you some examples of where I think
14 they have gone far beyond what was expected.

15 In Eugene, Oregon, about 10 days to two
16 weeks ago there was a large West Coast gathering of
17 Vietnam veterans.

18 I was asked to go out, but unfortunately had
19 another commitment, and I couldn't go. On very
20 short notice--and my notice was very short--I called on
21 two of our environmental physicians, one at Palo Alto and
22 one at our VA Hospital in Seattle, Washington.

23 They leaped to the opportunity. This was on
24 the Easter weekend, the Saturday before Easter--not a very
25 convenient time.

1 They both went out very willingly and gave of
2 their time to conduct an educational conference on Agent
3 Orange. And that is just one example of many that I have.

4
5 Not only are they dedicated to the program,
6 I think they are knowledgeable. My impression is that
7 many of them have gone out and educated themselves.

8 We constantly get requests for materials. I
9 wish we could provide them with more material. That
10 is basically what I had this part of the agenda devoted
11 to. I want some help from you as to what more
12 additional information we can be providing them, and how
13 we should be providing it.

14 DR. MOSES: Why don't you use them as traveling
15 road show?

16 DR. SHEPARD: They do that all the time.
17 The environmental physicians go out and educate each other.
18
19 They often visit each others' facilities. And we encourage
20 that whenever possible.

21 I think that has been a very useful dis-
22 cussion. I would now like to open up the discussion to
23 the floor.

24 COMMENTS AND DISCUSSION

25 DR. SHEPARD: I have a question from Peter

1 Kahn which I think we have already dealt with, and we will
2 certainly go into it in more detail this afternoon.

3 Todd Ensign, from Citizen Soldier, asks of Dr.
4 Striegel: "There are, of course, no studies of direct
5 effect on humans. How does he characterize the Dow-
6 financed work of Dr. Albert Kligman on prisoners in
7 Philadelphia? Is his work part of the literature being
8 reviewed?"

9 Unfortunately, I don't think Dr. Kligman ever
10 published his results; but Jim, would you like to address
11 that?

12 DR. STRIEGEL: Yes.

13 We do have access to the information about
14 Dr. Kligmann's work from some testimony that was provided
15 to the Environmental Protection Agency, and that is
16 included in our data.

17 DR. MOSES: That brings up an interesting
18 question about how much unpublished data there is. When
19 you were here before you said that there was going to be
20 no unpublished, right?

21 DR. STRIEGEL: No. The mandate we have is to
22 consider the published literature; however in cases like
23 Kligman, being a perfect example, studies where there is
24 something controversial that we know of, we make an
25 effort to get those in.

1 DR. SHEPARD: Thank you.

2 Is there any other discussion, comments,
3 questions from the floor?

4 I would like to recognize Jon Furst, who
5 is, I believe, the President of the National
6 Veterans Task Force on Agent Orange.

7 MR. FURST: The chairman.

8 DR. SHEPARD: Jon, what can you tell us
9 about the upcoming meeting? Why don't you come up here
10 and have a seat?

11 MR. FURST: Many of you are familiar with the
12 Task Force. Ron De Young was the representative of the
13 Task Force.

14 It is a coalition of about 25 groups at this
15 point. We are having a conference at American University
16 here in Washington on Saturday and Sunday of the Memorial
17 Day weekend, that is May 23rd and 24th.

18 There are a number of people who will be there:
19 the Stellmans--some of you are aware of Dr. Jean and Dr.
20 Stephen Stellman.

21 Dr. Barry Commoner has expressed some interest;
22 but I won't commit.

23 The idea was to provide a forum where veterans
24 could be exposed to people who are familiar with the
25 literature in various ways; not only the medical literature

1 and the scientific literature and what is and is not
2 known and what is expected, et cetera, but also the legal
3 and the legislative, and all of the various efforts that
4 are ongoing from veterans' standpoints on small scales
5 to State-size scales to national scales, et cetera.

6 We hope that it will be an extremely profitable
7 situation as far as information goes for the veterans
8 themselves.

9 We are inviting the veterans, we are inviting
10 the veterans' family members, we are inviting all inter-
11 ested individuals in the community who can attend.

12 I am able to inform you that preregistration
13 can be accomplished by contacting our conference coordin-
14 ator in New York.

15 Professionals and others are requested to pay
16 a \$40 registration fee. Veterans assistance organiza-
17 tions are requested to pay a \$15 fee; and veterans are
18 requested to pay a \$10 fee.

19 Preregistration, if you will bear with me I
20 will read it once slowly so as not to take up your time.

21 "Preregistration can be accomplished by con-
22 tacting Ms. Ruth Schaeffer--S-C-H-A-E-F-F-E-R. She is
23 the task force's conference coordinator. She is avail-
24 able at the Veterans Affairs Office, City University of
25 New York, 535 East 80th Street," and I recommend that

1 you add after the East 80th Street "Caldwell" so that
2 the Post Office knows what building, "New York, NY 10021.
3 Her phone number is (202) 794-5757.

4 "There is an additional \$5 fee charged if
5 preregistration is not accomplished."

6 DR. KEARNEY: We are quite interested in this.
7 Do you have any paper on that? Could you provide, perhaps
8 the committee members with some background on that? A
9 list of speakers or registration or any information you
10 have would be helpful.

11 MR. FURST: Sure. I will get things to you.
12 I have the addresses here.

13 DR. KEARNEY: Very good. Thank you.

14 MS. JORDAN: I was given a number at A.U. where
15 I could call and get any information I wanted on that.
16 Do you have that number?

17 MR. FURST: Yes. Actually I can be reached.
18 My wife and I have been in town for a month, and we are
19 working at A.U. now, and we will be there until after
20 the conference.

21 You will forgive us for our untidy timeliness--
22 we are living out of a suitcase and have been for a month
23 and will be for another month.

24 You can reach us at 686-2741 in Washington.
25 That phone is provided by the graciousness of the National

1 veterans Law Center, which is allowing us a place to spread
2 our paperwork.

3 Thank you very much.

4 DR. SHEPARD: Are there any other questions
5 for Jon?

6 [No response]

7 DR. SHEPARD: Thank you very much, Jon.

8 Mr. Kaatz has forwarded a question, and I must
9 confess that I cannot quite make out the first one. Would
10 you like to ask the question directly, Mr. Kaatz?

11 MR. KAATZ: Well, it's more of a topic, maybe,
12 for the panel to think about, more than anything else.

13 It would seem to me that if you are looking
14 primarily for sources of topological insult in trying to
15 examine a veteran, you are never going to find it in the
16 examinations that are being conducted.

17 Number one, logic dictates that when you have a
18 situation where we are concerned about the issue of
19 teratogenesis, particularly of herbicides, you are going
20 to examine the veteran; but you are going to examine the
21 child and you are going to examine the spouse.

22 Maybe you are not going to physically examine the
23 spouse and the child, but at least they should have done
24 something to obtain general releases from these veterans
25 in order to get the medical records of those veterans who

1 are concerned about birth defects in the children,
2 especially where there are actual cases.

3 Now, I am a veteran with two children, both of
4 those children have birth defects; and I have been some-
5 what critical in the last year, as Dr. Shepard and some
6 of the other people on the panel know, as to what has been
7 going on.

8 Personally, I don't see where Agent Orange comes
9 into the picture in most of these cases; but what I am
10 saying is that if the VA had gone out in the very begin-
11 ning / and conducted a comprehensive physical examination, to include a
12 genetic study on the veterans, / and had taken a / look at the comprehensive
13 and medical child's birth/records, and had taken a look at the spouse's
14 medical records, you would probably eliminate about 70-80
15 percent of the cases.

16 I have two children who are in a program with
17 505 other children at a / major medical center. The children
18 go there on a regular basis; we have full-time staff of
19 competent / doctors and geneticists, and everything else that is needed.

20 children
21 There are veterans/in that program, and the
22 veterans/are not treated as an issue of Agent Orange. One
23 of the things that upsets me and upsets a lot of veterans
24 and parents around this country is the fact that there is
25 a lot of hype--and I can only call it "a lot of hype"--
being put out by some veterans organizations that have

1 actually terrorized parents with disinformation. This
2 is completely uncalled for. That's one problem.

3 So we have a group of fathers or parents going
4 over to the VA, expecting to get an examination that is
5 going to bear out some type of information as to say
6 whether or not they should have children in the future,
7 or "Should my wife have another child? Or should she
8 abort her next baby?" and so forth. This has terrorized
9 the parents.

10 Most of the fathers / children who have birth defects,
11 complex medical disabilities --we are working people, we
12 go to work, we are involved in business--it is usually
13 the wives who are taking the children to various programs
14 around the countryside.

15 The wives get exposed to one or two veterans
16 groups who visit these programs/and say, "Well, did
17 you see this report? Agent Orange causes cancer, and
18 Agent Orange causes this; and dioxin that is stored in
19 your /fat tissue//^{husbands and} is going to be transferred in sperm to
20 the wife, and you are going to have a child who will have
21 a birth defect."

22 That's when I became involved in this issue. I
23 blew my top. A group of fathers in one program got
24 together and said, "Look, there is not going to be any
25 more of this terrorization of wives or families in the

1 area that we are in. We don't allow it, number one."

2 Number two, in the Veterans Administration,
3 somewhere along the line, the people around this table are
4 going to have to forget about these epidemiological
5 studies for the moment and go back to the very, very
6 basics--and I have been dealing with this issue for 10
7 years--and that's (1) doing an examination on the veteran
8 that is comprehensive, and /doing at least a genetic study.

9 Now, Dr. Moore, whom I respect very highly and
10 have read a lot of his studies and a lot of information
11 that has come out of NIH, says, "Logic dictates that if
12 there was some permanent damage to the spermatogonial
13 cells," that would be an issue of concern here as far as
14 teratogenesis." I don't see it. I don't see that damage,
15 in my own case, there is no scientific data to support it
16 and I don't see it among the veterans in our program, or
anyplace else.

17 Now, logic also dictates that if you do a
18 genetic study on the child, even if you don't do a genetic
19 study on the veteran, it might show some form of genetic
20 effect. We are not saying that /either.
this could indicate cause and effect

21 What we are saying is that/^{there are} a hell of a lot of
22 other medical problems among veterans may be virally-
23 related, may be related to dormant viruses or a number
24 of other factors; but nobody is going to pin it down
25 until/^{you} take the veteran and look at the veteran as a

1 family group, because that is what we are all concerned
2 about--we are concerned about children here; we are not
3 so much concerned about ourselves.

4 If the VA says I am a very healthy man, if they
5 send me a letter, okay--I am healthy. I am concerned about
6 the children more than anything else.

7 The VA does not have any outreach program where
8 they say to the veteran, "Okay, here we have a child,^{involved in the issue.} You
9 have two children; you were exposed to Agent Orange," and
10 I was--I know what the ^{herbicide} is.

11 I don't see the VA referring these parents or
12 referring any of these children to any kinds of medical
13 programs. And this is a problem, a very big problem,
14 for this reason.

15 I came in contact with the president of one
16 veterans organization who spent five hours in my house.
17 He told me how he ^{represented} / 10,000 veterans in his organization.

18 He was going out there and trying to set up a
19 clinic in humanistic medicine to examine veterans and
20 children so they could be treated.

21 Now the major issue here is treatment of the
22 veteran. You know, most of us are willing to sit back
23 and say, "Okay, you people are scientists. Five or ten
24 years from now you might come up with some answers."

25 But in the meantime the major concern among the

1 veterans is the children--not anything else, not even his
2 own health in most instances, but the children.

3 And until such a time that somebody sits down
4 and establishes a protocol for doing these medical exam-
5 inations the way they should be done -- and I listened
6 somewhat to what Dr. Moses says. I agree with what she
7 has said in context: it is not being done right. Improper
8 instructions are going out to VA doctors, and
9 the doctors in a lot of cases are not asking the kinds of
10 questions that should be asked when we are concerned with the
genetic insult.

11 Particularly when the veteran walks in the door
12 and has a child who is disabled as a result of birth defects

13 that's probably the reason he is there.

14 Now, I have talked to a lot of these people
15 and have observed first hand what / goes on at VA facilities. He walks
16 out and two weeks later gets a letter saying he is
17 perfectly healthy, okay? Fine. He is perfectly healthy;
18 but he still has a child who has a problem and the veteran may
also have a medical condition.

19 Unless the issue is addressed to that child
20 we are never going to solve this problem, okay?

21 In my own case, and in cases of the veterans
22 who are affiliated with our parent organization in this
23 one medical center, we don't see the Agent Orange as
24 being an issue here. We do see a major national health issue
concerning care for the veteran and child.

25 What we do see is a hell of a lot of other

1 medical factors that are affecting veterans. The VA is
2 not addressing them. The veteran walks out with a letter,
3 and that's all he has.

4 The VA doesn't say, "Okay, we have a medical
5 facility in this county that can provide genetic counsel-
6 ing for the children, that can do some genetic studies
7 on them."

8 It's a very simple thing to do. It's a smear
9 from the throat or it's a blood test--you grow a culture.
10 Something very, very simple that should have been very
11 basic, in the very beginning. It has not been done.

12 The thing that disturbs me most of all is that
13 the Veterans Administration doesn't even have a facility
14 anywhere in the United States capable of doing a single
15 genetic study. You know, I just find that incredible.

16 Now, if they don't have it, they should have a
17 doctor sitting there saying, "Okay, you have children or
18 a child--what's wrong with the child." Let's get a general
19 release on the child's medical records; get a general
20 release on the wife's medical records; we'll get a panel
21 of doctors at a VA Hospital who are experts in various
22 fields around the table, and we will go through these
23 medical records.

24 You will probably find out that a lot of cases
25 involving / ^{cerebral palsy} , spinal bifidus , and a dozen other

incapacitating diseases are probably malpractice in some cases, or other incapacitating conditions that /have nothing to do whatsoever with Agent Orange.

Of all the veterans that I have seen--and I have talked to several hundred personally--I do not see Agent Orange as the issue here.

Until the people around this table sit down and structure and define a physical examination that has to be done to include comprehensive review of the medical records of the veteran, spouse and child the issue will never be resolved!

I think you can eliminate about 70 percent of the claims, and maybe even higher. There are doctors in this country, experts in this country, that I've talked to who are seeing a large number of cases of cerebral the children of one prominent palsy among /veterans. In most cases, according to/neuro- surgeon in this country, 70 percent of those cases are the result of malpractice, and have nothing to do with Agent Orange whatsoever.

But what do we see? We see a load of hype in the newspaper, a bunch of organizations handing out literature about Agent Orange, and the parents become terrorized. And the next thing you know the whole fiber of that family is destroyed.

DR.SHEPARD: Excuse me, Mr. Kaatz I am going to have to interrupt you. I appreciate your point,

1 and it is a need that we have recognized.

2 MR. KAATE: I have one other point.

3 DR. SHEPARD: I'm sorry, the time is up.
4 We have one other question. If we have time then we will
5 come back to you, okay?

6 But I do want to address the concern about the
7 genetic counseling. It has not gone unrecognized as a
8 need and as a void. I think that we need to start taking
9 some initiatives in terms of filling that void.

10 I have a question here. I think we will have
11 to ask Dr. Shibko it if he can, since he is representing
12 the EPA today.

13 This is from Mr. Ryan Kruger: Why were the
14 cancellation hearings on 2,4,5-T stopped? And what is
15 the status of the out-of-court settlement that has been
16 reported to be appearing?

17 DR. SHIBKO: I think you mean Dr. Spencer.

18 DR. SHEPARD: I'm sorry.

19 DR. SPENCER: I wish he could answer it.

20 [Laughter]

21 DR. SPENCER: As a matter of fact I did get in
22 touch with a lawyer last night, at your request in fact,
23 and unfortunately I don't have anything to report to you;
24 because, probably a good analogy would be, if our State
25 Department had as good a tight lip, we would probably not

1 be in as bad a shape as these people who were running it,
2 because I got absolutely nothing from them.

3 I can only say that they are negotiating, hope-
4 fully for the good of the people, that they are supposed
5 to go into report to the judge whether to continue the
6 hearing for cancellation or whether to continue negotia-
7 tion, or just what they are going to do, as of this
8 Friday.

9 That is, in essence, all that I know about it.

10 DR. SHEPARD: I think we need to appreciate
11 the fact that this has been a matter under considerable
12 investigation, and we are in a sense putting Dr. Spencer
13 in a little bit on the spot to speak for the EPA.

14 Perhaps suffice it to say that the hearings have
15 been suspended, and the parties are in the process of
16 negotiation.

17 Are there any other questions from the floor?

18 [No response]

19 DR. SHEPARD: All right, Mr. Kaatz, you have
20 it.

21 MR. KAATZ: In this country, right now, there is
22 a \$40 million program called the NTP, or National Toxicol-
23 ogy Program.

24 I don't see that program being/ effectively integrated into
25 concerning veterans and this issue/ of Agent Orange. It would seem to me that/ some based on

1 studies and the protocol that has been
2 established around this table, for studies
3 are duplications of what is going on in the
4 National Institute of Environmental Health, what is going
5 on in the FDA, what is going on in the Department of
6 Agriculture out there in Pine Bluffs.

7 When I find that people like Dr. Young, / Department of Agriculture
8 especially, who is the head of the Division of Teratogeni-
9 sis, has not even consulted on matters concerning Agent
10 Orange, particularly when they are concerned primarily
11 with 2,4,5-T and other types of pesticides and insecti-
12 cides, I don't see that \$40 million integra-
13 tion into this picture.

14 It seems to me that a lot of these problems
15 are already in the process of being examined by the

16 National Institutes of
17 government Health and other / laboratories under this \$40 million NTP
18 program.

19 the VA is
20 I see that / doing a paper chase on worldwide
21 and review literature, when we have a National Library of Medicine,
22 we have a National Institute of Health that has a computer
23 division specifically designed to establish and set up
24 models for computers, and doing epidemiology surveys and
25 everything else.

I see a tremendous amount of duplication and a

1 lot of wasted effort, when the VA could be turning to
2 certain agencies of the government rather than giving
3 contracts out duplicating the efforts
of other government institutions.

4 If you take the Annual Report of the National
5 Institutes of Health, you probably have the resources of
6 some of the best / medical and scientific experts
research programs, in the world.
7 I don't see the integration of / resources available,
effective nor do I see the
8 /integration of the National Toxicology Program in solving
the overall issue.

9
10 DR. SHEPARD: Can I answer your question?

11 MR. KATZ: Yes.

12 DR. SHEPARD: Okay.

13 We had hoped that Dr. Moore would be here today.
14 He is a member of this committee and is the Deputy Director
15 of the National Toxicology Program.

16 He has recently published the results of a
17 laboratory study that he conducted specifically on the
18 subject of genetic effects that might be expected to
19 result, in which he exposed a group of male mice to the
20 ingredients of Agent Orange.

21 So there has been some effort. You have heard
22 from members of the National Cancer Institute, which is
23 an arm of NIH. Dr. Lingeman, specifically, is a member of
24 our committee. She works there.

25 And Dr. Cantor was here today from the AFIP.

1 So I think it is safe to say we have made some
2 efforts to bring in other Government agencies. One effort
3 that you may not be aware of and which I should have
4 alluded to earlier is the very good work of the Inter-
5 agency Work Group, which represents a number of Government
6 agencies including the VA, DOD, and the Department of
7 Health and Human Services. Dr. Moore is the Chairman of
8 the Science Panel of that group

9 So I think there has been an effort to integrate
10 a lot of Government efforts.

11 You commented about the National Library of
12 Medicine in doing literature searches. The contract that
13 Dr. Striegel alluded to earlier and reported on is not
14 a literature search. As far as I know nobody has under-
15 taken an indepth analysis of the world literature on this
16 subject; so this is really a first. We went the contract
17 route because we thought we could get it most quickly that
18 way, and probably most cheaply.

19 So that may, in part, answer some of your
20 questions, some things that you simply weren't aware of,
21 Mr. Kaatz.

22 MR. KAATZ: What I am saying is, if you take the
23 Annual Report of the National Institute of Health, and
24 if you break that annual report down and see the kinds of
25 services that can provide to the

1 American people in this country, I see no need to go out
2 and award contracts to anybody.

3 What I see here is a lot of duplication of
4 research efforts and a lot of very poor coordination.

5 Now, one example of this is the CEW example.
6 If you go back to ^{military history of} World War II and look at the old 'War
7 Research Service' that George Merck headed--he was a very
8 brilliant man--he brought together 3900 experts who
9 examined the chemical warfare programs of two nations,
10 Japan and Germany.

11 As an end result of that they came up with a
12 lot of peaceful uses of chemicals, ^{in agriculture} namely 2,3,4,5-T. Now,
13 what I do not see here with this Agent Orange issue is the
14 kind of effort that George Merck made during World War II
15 on bringing the kind of people together to resolve this
16 issue at hand.

17 I think if they were brought together the issue
18 could be resolved. I beg to differ. While there are
19 representatives here of many of the Institutes within
20 National Institutes of Health, I do not see the key experts

21 in this country involved in this issue that have
22 the experience or the know-how, or have been working for
23 the last 30 or 40 years in the field of toxicology.

24 Now, I have talked to a few of them, some of
25 them being Nobel Prize winners. They are not here; and
that's what concerns me.

If we had a Chemical-Nuclear-Biological attack tomorrow morning, everybody in the whole country would be concerned about ^{the subject of} teratogenesis, and they would bring these people together and say, "Okay, we have a potential ^{to humans,} vulnerability / let's deal with the situation."

I don't see that here. I don't see the kind of effort that was made during World War II in solving the present problems. It's just not here. It's not at this table.

The agencies that should be here are not here; the people that should be representatives from the National Institutes of Health are not here; and I see \$40 million dumped into a National Toxicology Program designed to solve problems like this.

If they can't solve a problem like Agent Orange, I don't know how they expect to solve any other kind of problem as far as toxicology in this country.

You have to get the people who know what they are doing together. Now, a lot of the people at this table are well-qualified; but what I am saying is that George Merck had 3900 people out there, and I think it's time that we try to fall back on some of those people. They are still around in this country. They know more about toxicology and chemical warfare and would be able to provide a significant contribution to solving this issue.

I think if anyone had an idea of what was going

1 on with herbicides some of those people should. They
2 doalt with the issues. They are the ones that turned
3 the herbicides over to the chemical companies for peaceful
4 uses in 1946; and that's the basic issue here.

5 DR. SHEPARD: Thank you, Mr. Kaatz. I
6 appreciate your comments.

7 Are there any other comments or questions?

8 [No response]

9 DR. SHEPARD: Well, thank you again for
10 your indulgence and participation in another very worth-
11 while meeting.

12 Thank you.

13 [Whereupon, at 12:05 p.m., the meeting was
14 adjourned.]

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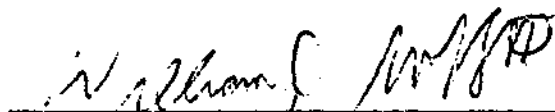
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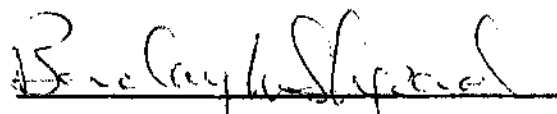
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C E R T I F I C A T E

This is to certify that the foregoing proceedings before the Veterans Administration, Advisory Committee on Health-Related Effects of Herbicides, Tuesday, May 5, 1981, were had as herein appears and that this is the original transcript thereof.


WILLIAM J. MOFFITT

I hereby certify that the proceedings and evidence herein are contained fully and accurately, as corrected.


BARCLAY M. SHEPARD, M.D.
Chairman, Advisory Committee
on Health-Related Effects of
Herbicides

June 30, 1981

Advisory Committee on Health-Related Effects of Herbicides Transcript of Proceedings

(Ninth Meeting

August 19, 1981)

VETERANS ADMINISTRATION

ADVISORY COMMITTEE ON HEALTH-RELATED
EFFECTS OF HERBICIDES

Veterans Administration
Central Office
Room 119
810 Vermont Avenue, N.W.
Washington, D.C.

Wednesday, August 19, 1981

The Committee met, pursuant to notice, at 8:30 a.m.
BARCLAY M. SHEPARD, M.D., Chairman, presiding

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PROCEEDINGS

CALL TO ORDER AND OPENING REMARKS

(8:30 a.m.)

DR. SHEPARD: Good morning, I think we'd better get started. We have a full agenda this morning. I would like to welcome you all once again to our quarterly meeting of the VA Advisory Committee on Health-Related Effects of Herbicides. It's an ongoing pleasure for me personally to continue this forum which I think serves a useful purpose in bringing together large segments of our interested population. We have here both scientists and representatives of veterans organizations. I think this forum affords the opportunity for a meaningful dialogue and I hope a useful one. We have some welcoming today. Jon Furst, has officially been designated a member of this committee. He is the chairman of the National Veterans Task Force on Agent Orange. Jon, it's a real pleasure to have you as a full-fledged member of our committee.

MR. FURST: Thanks.

DR. SHEPARD: We also would like to recognize Major Al Young who has come to us on loan from the Air Force. Many of you know Al Young to be a leading and very knowledgeable authority on the subject, having done much of the scientific work himself and having contributed extensively to the whole

body of knowledge as it relates to this complex issue. So we're very pleased to have Major Young with us on our staff and we are very grateful to the Air Force for loaning him to us.

We also would like to recognize a number of distinguished visitors who are with us this morning. First of all, Dr. Robert Bernstein, the Commissioner of Health for the State of Texas. Dr. Bernstein had a distinguished career in the Army and was, I believe, at the time of his retirement, the Commanding General of Walter Reed Army Medical Center. We are very pleased to have you with us this morning, sir. He will address the committee later on in the program. With him are some other representatives from the State of Texas, and we are very pleased to have them with us. Representative Larry Shaw, I haven't met him yet, but, he may be here. If he is, I wish to thank him for his presence. He was the drafter of the Texas legislation. In an ongoing attempt for us to act as a clearinghouse for information with various state organizations which have taken an active role in the concerns as they relate to veterans and Agent Orange, we welcome him.

We will be having a meeting this afternoon in my office with some of the representatives of the state organizations.

Another individual whom we'd like to recognize is Mr. George Brett who is the Executive Director of the Agent Orange Commission in the State of New York. George will be with us a little later on. We'd also like to recognize Mr. Mike Leaveck who represents the State of California. As you know, California has recently initiated legislation for efforts relating to the Agent Orange issue.

Since our last meeting, as you all know I'm sure, we have a new Administrator of Veterans Affairs. Mr. Robert Nimmo from California has been duly installed as the new Administrator. He wanted very much to be with us this morning, but because of conflicting commitments, he could not. However, he has sent you his greetings in the form of a tape and we'll now ask that that tape be played.

MR. NIMMO: MESSAGE FROM THE ADMINISTRATOR (tape) Well the fact that I'm not able to be with you today is my loss, not yours. I'm much more interested in learning your thoughts on Agent Orange than giving you mine.